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NEWS

Caya™ (SILCS) diaphragm receives regulatory approval in Europe

The SILCS diaphragm, marketed as Caya™, is now on the market in Europe, after receiving regulatory approval in June. The first new cervical barrier method to receive approval and enter the market in more than ten years, SILCS features a one-size-fits-most design that eliminates the need for fitting, a significant simplification that will bring the diaphragm to women in settings where fitting services are difficult to obtain or unavailable. The design contains features such as grip dimples to guide users where to squeeze for insertion and a removal dome to make removing the device easier. SILCS is molded out of silicone, which makes it longer-lasting than latex diaphragms and suitable for those with latex allergies. It was designed through a partnership between PATH, a global health nonprofit, CONRAD, an organization dedicated to designing new reproductive health products, the United States Agency for International Development, and others. Caya™ will initially be available through health providers and pharmacies in five European countries, and later expanded to additional markets.

The next step for the SILCS team is regulatory submission to the United States Food and Drug Administration for market approval in the United States. The team is also working with research partners in Uganda, India, and South Africa to gather information on opportunities and challenges for introducing SILCS in low-resource settings. See the the **Featured Research** section in this newsletter for our special feature on SILCS, including more information on these efforts and other new research related to SILCS.

For more information about the SILCS diaphragm and this exciting development, visit the **PATH website**.

Woman's Condom South African Bureau of Standards (SABS) certification mark

In May 2013, the Woman's Condom received the **South African Bureau of Standards** (SABS) certification mark, an assurance to buyers in South Africa that the product meets international safety and quality requirements.

PATH and its manufacturing partner, Shanghai Dahua Medical Apparatus Company (Dahua), are working with a local distribution partner to bring the Woman's Condom to South Africa; the SABS certification mark represents a critical step toward introduction. Combined with Shanghai Food and Drug Administration approval (2011) and the CE Mark (2010), the SABS certification mark continues to build confidence about the quality of the Woman's Condom among donors, purchasers, and potential users.

Global Female Condom Day 2013 - September 16th

September 16 marks the second annual Global Female Condom Day - a day of education and advocacy dedicated to female condoms. Last year, thousands of individuals and nearly 200 organizations from 26 countries participated. **Join us this year by pledging to take action.**

Female condoms are powerful tools for pleasure and prevention. They empower and protect. But more people need to know about female condoms and be able to access them. You can help make that happen! Advocate for female condoms on Global Female Condom Day.

By taking this pledge, you are promising to take action along with female condom advocates across the globe on September 16. As the day of action approaches, we will let you know ways - large and small - that you can be a part of the global movement for female condoms.

The Female Condoms Are_____ Film Contest winners announced at Women Deliver 2013

The Female Condoms Are_____Film Contest announced its winners! Filmmakers submitted dozens of films from five continents, and 12 finalists were chosen. These short films were screened at the Female Condoms Are_____ Film Festival on May 28, 2013 in Kuala Lumpur, Malaysia at the Women Deliver 2013 conference. The winning film, from Pathfinder International, is titled "Female Condoms Are My Power, My Protection, My Pleasure!" and follows Deolinda, a volunteer activist in Mozambique who promotes the female condom, and Benjamin, another activist who works to get the support of men. The second place winner is a drama from Cameroon, titled "Female Condoms Are Preferable," and two films, "Female Condoms Are Pretty Nice" from Malaysia and "Female Condoms Are a Woman's Bargaining Power" from Kenya, tied for third place. Many of the films emphasized that female condoms empower women by giving them more control over their sexual and reproductive health.

To view these engaging and informative films and to learn more about the Female Condoms Are_____ Film Contest, go to: **www.femalecondomfilm.org**.

FEATURED RESEARCH

The SILCS Diaphragm

In this section, we highlight several recent, ongoing, and planned studies related to the SILCS diaphragm.

Contraceptive effectiveness and safety study of the SILCS diaphragm: The pivotal contraceptive effectiveness study

Location: United States

In 1994, PATH, an international nonprofit organization based in Seattle, began development of a single-size silicone contraceptive diaphragm, incorporating input from users and clinicians to identify and address issues that have limited the use of currently available diaphragms. The SILCS diaphragm was developed based on user evaluations in multiple sites in the US. Additional testing was performed in South Africa, Thailand, and the Dominican Republic to confirm user acceptance. Results of the CONRAD Phase I postcoital study found the single-size SILCS diaphragm used with nonoxynol-9 during intercourse was comparable to a traditional diaphragm and prevented progressively motile sperm from reaching cervical mucus (Schwartz et al. 2008). Results of a study using magnetic resonance imaging to evaluate the fit of the SILCS in vivo indicate that the device fits women of varying parities and body sizes (Yang et al. 2007).

CONRAD then evaluated the SILCS diaphragm in a contraceptive effectiveness, safety, and acceptability study implemented at 6 centres in the US. The study recruited 450 couples who used the single-size diaphragm with a contraceptive gel as their primary contraceptive method for six months. Three hundred women used the single-size diaphragm with BufferGel (an investigational new drug that was being developed at that time as a contraceptive gel and also as a microbicide to potentially protect from STIs, including HIV). The remaining 150 women used the single-size diaphragm with Gynol II (a contraceptive gel that contains nonoxynol-9). This study was designed to be similar to another recent study of a traditional diaphragm used with BufferGel (Barnhart et al. 2007) so the study results could be compared.

Results from this study of the SILCS diaphragm with contraceptive gel confirmed that contraceptive effectiveness is similar to results from the most recent study of a traditional diaphragm used with contraceptive gel (Barnhart et al. 2007). Results from this study were presented in the US at the 2011 Reproductive Health conference and confirmed that the single-size diaphragm fits most women, and performs similarly to a traditional diaphragm.

The clinical portion of the study was complete as of November 2009. Results from this study were submitted to the US FDA in 2012, and will support a regulatory application for the SILCS diaphragm. A manuscript of the study results is being developed.

This study was sponsored and conducted by CONRAD, and funded by USAID.

Related Publications:

Barnhart KT, Rosenberg MJ, MacKay HT, et al. Contraceptive efficacy of a novel spermicidal microbicide used with a diaphragm. *Obstetrics and Gynecology.* 2007;110(3):577-586.

Schwartz JL, Ballagh SA, Creinin MD, et al. SILCS diaphragm: postcoital testing of a new single-size contraceptive device. *Contraception.* 2008;78:237-244.

Yang C, Maravilla KR, Kilbourne-Brook M, Austin G. Magnetic resonance imaging of SILCS diaphragm: anatomical considerations and corroboration with clinical fit. Contraception. 2007;76(3): 238-244.

Related Presentations:

Schwartz JL, Weiner D, Lai JJ, et al. SILCS pivotal data: implications for MPTs. Presented at the 2011 Reproductive Health conference. Las Vegas; September, 2011.

Schwartz J, Kilbourne-Brook M, Frezieres RG, et al. Over-the-counter provision of the SILCS Diaphragm. Presented at the International Conference on Family Planning, Kampala, Uganda; November 2009.

An exploratory, randomized, cross-over (MRI) study of microbicide delivery with the SILCS diaphragm compared to vaginal applicator

Pre-Phase I

Location: University of Pennsylvania, United States

This was an exploratory, non-blinded, randomized, crossover study to assess the feasibility of the SILCS diaphragm as a microbicide (BufferGel®) delivery system and to assess overall user acceptability. Secondary objectives included assessing the gel coverage of the upper vagina (above the pelvic diaphragm) and the entire vagina using three methods of application, assessing distribution of the gel before and after simulated intercourse (immediately after and 6 hours after), and assessing the initial acceptability of the SILCS microbicide delivery system compared to pre-filled applicators. Nine women participated in this study; three women pre-tested the study procedures and six women completed the main body of the study. A subset of three participants completed an additional sub-study to clarify findings. The publication cited below reports on results from the final sub-study.

This study, conducted between February 2009 and March 2010, was implemented by the University of Pennsylvania Women's Health Clinical Research Center and The Miriam Hospital/Brown University Centers for Behavioral & Preventive Medicine, and sponsored by PATH. It was funded by USAID.

Related Publications:

Pentlicky S, Rosen M, Coffey PS, Kilbourne-Brook M, Shaunik A, Schreiber CA, et al. An exploratory, randomized, crossover (MRI) study of microbicide delivery with the SILCS diaphragm compared to a vaginal applicator. Contraception 2013; 87(2): 187-92.

ABSTRACT

Background: Microbicide gels studied for HIV prevention often are delivered via a single-use vaginal applicator. Using a contraceptive diaphragm such as the SILCS diaphragm for gel delivery could have advantages, including lower cost and additional pregnancy prevention.

Study design: We performed an exploratory, nonblinded, randomized, crossover study among healthy, sexually active, nonpregnant women. Using BufferGel, we evaluated three microbicide delivery methods for gel distribution and retention: SILCS single-sided gel delivery, SILCS double-sided gel delivery, and a vaginal applicator (without SILCS). Magnetic resonance images were taken at baseline, after gel insertion, and immediately and 6 h after simulated intercourse. Three women completed all gel delivery methods described in this article.

Results: Magnetic resonance imaging analysis indicated similar gel spread in the vagina among all three methods. SILCS single-sided gel application resulted in the most consistent longitudinal coverage; SILCS double-sided gel application was the most consistent in the transverse dimension.

Conclusions: Gel coverage was similar with all three methods. These results suggest that the SILCS microbicide delivery system is comparable to vaginal applicators for delivery of gel products intravaginally.

Health systems and market opportunities for SILCS as a barrier contraceptive in India

Market introduction study

Location: Delhi, Mysore, and Rajasthan, India

This assessment is exploring opportunities and challenges for future introduction of the SILCS diaphragm in India. First, the study team interviewed national stakeholders in Delhi and state-level stakeholders in two states in India, including family planning/sexual and reproductive health providers and members of NGOs. They also conducted focus group discussions with potential SILCS users. Using a systems perspective, this assessment will characterize issues and attitudes that will need to be considered when planning for future introduction of this non-hormonal barrier contraceptive in this context. In addition, this assessment will outline the

regulatory pathway, potential service delivery scenarios, target audiences, and communications and training materials needed to support future introduction.

The qualitative data collection was conducted in November 2012-March 2013. The transcripts from the FGDs are currently being translated and analyzed. A final report of the findings and recommendations is scheduled for August 2013.

This assessment is being conducted by Ashodaya Samithi of Mysore in Karnataka state, India, and Katharine Shapiro, a reproductive health consultant, in collaboration with PATH. This assessment is funded by USAID.

Market assessment of SILCS as a reusable delivery system for microbicide gel in South Africa

Market introduction study

Location: KwaZulu Natal and Western Cape, South Africa

This study is designed to assess opportunities and challenges for future introduction of the SILCS diaphragm in South Africa both as a non-hormonal barrier contraceptive and as a reusable delivery system for microbicides, such as Tenofovir gel. Through desk research, key informant and in-depth interviews, and service delivery facility assessments, the study team will identify policies, regulatory guidance, service delivery scenarios, and training requirements to plan for future introduction of the SILCS diaphragm. Focus group discussions with potential users will help identify which market segments are most likely to be interested in this non-hormonal barrier method.

This study will take place from October 2012-September 2013. The desk review of the policy and regulatory environment for future introduction was completed in February 2013. Ethical approval for the qualitative component of this activity was received in May 2013, and the key informant interviews and focus group discussions are planned for June-August 2013.

The study is being conducted by researchers at MatCH located in Durban, South Africa, in conjunction with PATH. This assessment is funded by USAID.

Postcoital barrier effectiveness study of the SILCS diaphragm with Contragel

Phase I PCT study

Location: United States

Clinical guidelines recommend that diaphragms be used with a contraceptive gel to increase effectiveness. Most commercially available contraceptive gel products contain nonoxynol-9 (N-9), and are only available in developed countries. Products with N-9 are no longer recommended for use in countries where women are at risk of HIV (see the **WHO guidance** or **RHTP fact sheet** on N-9). Alternative contraceptive gel products that do not contain N-9 are needed for use with diaphragms, especially for women in countries where N-9 products are no longer available, or for women who cannot or do not want to use N-9 gel.

Contragel is a lactic acid based contraceptive gel product approved in Europe for use with cervical barrier products such as diaphragms and cervical caps. It has CE Mark certification and has been marketed for nearly 20 years primarily in Europe, where it has a good safety and acceptability profile. It has never been submitted to the US FDA for market approval.

In 2012, CONRAD evaluated Contragel safety in animal studies. No safety concerns were found. This laid the groundwork for a clinical study in humans. CONRAD will evaluate SILCS used with Contragel in a postcoital study of barrier effectiveness.

Protocol development is in process. The study is planned to begin in late 2013 or early 2014 at one or two centers in the United States and to continue through 2015.

The study is being conducted by researchers at CONRAD and is funded by USAID.

Late-stage development of multipurpose prevention technologies: SILCS as a reusable delivery system for Tenofovir gel

Phase I safety study, followed by a PCT study

Location: United States

The SILCS diaphragm is designed to fit most women, is easy to insert and remove, and is comfortable for both partners. Clinical testing of the SILCS diaphragm has shown good safety, function, acceptability, and effectiveness. Tenofovir (TFV) 1% gel is the first vaginal microbicide proven to be safe and efficacious in the primary prevention of HIV-1 in women (Abdool Karim Q et al. 2010). A contraceptive diaphragm could be a safe and inexpensive delivery system for microbicide gel while also providing contraceptive protection. SILCS, as an improved diaphragm, could be a reusable delivery system for TFV 1% gel and could provide advantages over the use of pre-filled plastic applicators used to deliver microbicide gel in clinical studies.

CONRAD is planning to implement two studies to evaluate the safety and effectiveness of SILCS when used with Tenofovir 1% gel:

- Study I: Phase I Safety, PK/PD Study of the SILCS Diaphragm Used with TFV or HEC Placebo Gel (clinical portion of study should last around 10 months)
- Study II: Phase I Postcoital Testing and Safety Study of the SILCS used with 2% N-9 or TFV Gel (clinical portion of study should last around 12 months)

Protocols are being developed for these studies, and appropriate regulatory applications are underway. CONRAD expects to begin the first of these studies in early 2014.

This study is being conducted by researchers at CONRAD and is funded by USAID.

Related publications:

Abdool Karim Q, Abdool Karim SS, Frohlich JA, Grobler AC, Baxter C, Mansoor LE, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*. 2010; 329(5996): 1168-74.

RESOURCES

Updated cervical barriers and female condom bibliographies

We are excited to share these updated resources with the CBAS community. Our bibliographies of the literature on diaphragms and cervical caps and on the female condom include the latest peer-reviewed articles published through May 2013. Both bibliographies can be downloaded on our website or by following the links below.

Female condom bibliography
Diaphragm and cervical cap bibliography

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Note: We are always updating our research listings on the CBAS website. Please contact us at info@cervicalbarriers.org with study updates or information on new research related to cervical barriers or female condoms.

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