


[Newsletter](#)
[Subscribe/Unsubscribe](#)
[Archives](#)

The logo for the newsletter, featuring the text "cbas Newsletter" in a large, white, sans-serif font. Below it, in a smaller font, is "published by the Cervical Barrier Advancement Society". The background is a dark teal color with a white wave-like graphic at the top.



CBAS is coordinated by
[Ibis Reproductive Health](#)

[Newsletter](#)
[Current Newsletter](#)
[Archives](#)
[Subscribe/Unsubscribe](#)
Volume 11, Number 1
September 2014
NEWS

Caya (SILCS) diaphragm cleared for marketing in the United States, approved for OTC sale in Canada



September 9, 2014—Today PATH, CONRAD, and Kessel announced that the Caya single-size diaphragm (called SILCS during design and clinical validation stages) has received United States Food and Drug Administration (USFDA) clearance for marketing. With marketing clearance, the next step is for Kessel, the privately held company responsible for the manufacturing and marketing of Caya, to identify and qualify a distribution partner for the US market. Kessel believes the diaphragm could be ready for a US launch in the next year. Caya will be available in the US by prescription through family planning providers.

Today's announcement follows approval this past May by Health Canada, the Canadian regulatory authority, for over-the-counter (OTC) sale of the Caya diaphragm in Canada. Distribution of Caya in Canada will initially be through pharmacy wholesale distributors and sub-distribution partners of the diaphragm's Canadian supplier, Trimed Supply Network Ltd., which will also sell directly to doctors, according to Trimed.

In addition to OTC availability in Canada, Caya received CE Mark regulatory approval in Europe in 2013, and is currently available in 14 European countries without prescription through family planning providers, pharmacies, and online stores.

Caya was developed by PATH, CONRAD, and partners at multiple sites with funding from USAID and private foundations to expand women's options for non-hormonal barrier contraception. The diaphragm features a one-size-fits-most design that eliminates the need for fitting, and also contains features such as grip dimples to guide users for insertion and a removal dome to make removing the device easier. Caya is molded out of silicone, which makes it longer-lasting than latex diaphragms as well as suitable for women with latex allergies.

Efforts are now focusing on market introduction in lower resource settings. Market research and health systems assessments took place in South Africa and India in 2012-2013 to outline regulatory pathways, potential service delivery scenarios, target audiences, and communications and training materials needed to support and inform future introduction. See the [ongoing research page](#) of the CBAS website for more information. Additional information on other upcoming research can be found on our [planned research page](#), including studies to evaluate the Caya diaphragm used with Contragel, the Caya diaphragm as a reusable delivery system for Tenofovir gel, and the use and acceptability of the Caya diaphragm compared to a standard applicator for delivery of a placebo vaginal gel.

Find more information here:

Caya: <http://sites.path.org/rhtech/silcs-diaphragm/>

Kessel medintim GmbH: <http://www.Caya.eu>

Other product updates
Ortho All-Flex Diaphragm

Over the past several months, there have been a number of other changes to cervical barrier method availability. One significant shift came with the discontinuation of the Ortho-All Flex diaphragm in the US by Janssen Pharmaceuticals, Inc. in December 2013. [See discontinuation letter](#). A Janssen representative told us by phone that the All-Flex may still be available in other countries, but that it needs to be confirmed by each Janssen country affiliate, and noted that the product is no longer listed on [Janssen's global website](#).

Milex Wide-Seal Diaphragm

In the US and many other countries, until the Caya diaphragm comes to the market, there is now only one diaphragm option, the Milex Wide-Seal, which is manufactured by Cooper Surgical. Previously, Milex diaphragms were only available through a physician or other qualified medical practitioner who had an account with Cooper Surgical. However, in part due to the discontinuation of the All-Flex, Cooper Surgical changed their policy in June 2014, allowing individual US pharmacies to establish accounts and order diaphragms directly for their customers. To date, Cooper Surgical has not proactively made pharmacies aware of this change. Patients in the US wanting to purchase a diaphragm locally from their pharmacy are advised to ask their pharmacist to establish an account with Cooper Surgical.

Reflexions Diaphragm

We have received reports that the Reflexions diaphragm, distributed by Williams Medical of the UK, has been discontinued. There has not been a formal announcement from Williams that Reflexions has been discontinued and we were not able to confirm this directly from the manufacturer. We are hoping to get confirmation from the manufacturer about the status of this product, and will keep you posted as we learn more.

Lea Contraceptivum

We have also received reports that the Lea Contraceptivum has been discontinued due to mechanical problems with the production machine, and that the manufacturer has chosen not to pursue the Lea Contraceptivum further. The Lea Contraceptivum is a silicone barrier with a removal loop and valve for the passage of menstrual fluid and cervical secretions. It comes in one size and is approved for up to 48 hours of continuous use. We are hoping to get confirmation from the manufacturer about the status of this product, and will keep you posted as we learn more.

Dance to Demand on Global Female Condom Day

September 16 marks the third annual Global Female Condom Day - a day of education and advocacy dedicated to female condoms. The female condom is the only woman-initiated method that offers dual protection against unintended pregnancy and sexually transmitted infections including HIV. Even though women and men around the world want access to the female condom, this important option is not widely available or accessible.

This [Global Female Condom Day](#) sexual health and reproductive justice advocates around the world are invited to unite and show their moves by dancing to demonstrate demand for female condoms.



Be a part of this dance MOVEMENT for female condoms. Mark your calendar and get out your dancing shoes for September 16! [Read more about the dance concept, sign up to participate, and start organizing your dance!](#)

Also, check out this great [advocacy toolkit](#) to help you get started, from female condom talking points, to instructions for organizing your dance and tips for social media outreach.

[Sign up today](#) to participate in the 2014 Global Female Condom Day Dance for Demand.

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 August 31, 2014. Both bibliographies can be downloaded on our website or by following the links below. Please let us know if you are aware of any publications that are missing from these resources.

[Female condom bibliography](#)
[Diaphragm and cervical cap bibliography](#)

ABOUT US

Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information

For more information, contact Kate Grindlay, CBAS Executive Director, at info@cervicalbarriers.org.

CBAS is coordinated by Ibis Reproductive Health.



We welcome comments or suggestions for future newsletter items. Please contact info@cervicalbarriers.org.

Forward email to a friend

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.

Join CBAS

- [Subscribe/Unsubscribe](#) to CBAS newsletter only
- [Archives](#) of the CBAS newsletter

To comment on anything you read in the CBAS newsletter or to contribute a story, event, or news item, please [email CBAS](#).

[Site Map](#) | [Privacy Policy](#) | info@cervicalbarriers.org