

Maggie Kilbourne-Brook, Senior Program Manager at PATH, shares the updates for the Caya® diaphragm below. For readers wondering what has been happening with Caya, the answer is lots!

Caya is the single-sized contoured diaphragm developed by [PATH](#) and research partners in multiple countries to expand women's options for non-hormonal barrier contraception. Caya gained regulatory approvals first in Europe, Canada, and the United States (2013-2014). As of 2020, Caya is registered and marketed in nearly 35 developed and middle-income countries. Caya is manufactured by [Kessel Medintim GmbH](#) of Germany and marketed through Medintim's distribution partners. In the United States, Caya is distributed by [HPSRx](#). Product information is available at the sites linked above.

Medintim implements a marketing survey annually to understand experiences of women using the Caya diaphragm. Survey results are helping break open long-standing assumptions about diaphragm users. For example, results indicate that women across a wide range of ages (18-35+ years), both single and in stable relationships, with and without children use Caya. Most respondents previously used hormonal contraception, but a small portion of respondents never used contraception before. Survey results for 2015-2018 are found at the Caya [website](#).

The Caya diaphragm is available over-the-counter in all countries except the United States, France, and Italy. Most women report learning about Caya from the internet, social media, or their friends, and about half of women report learning to use the Caya on their own after reviewing the instructions while about half visit a family planning provider to ensure the device fits.

Since diaphragms have not been included in provider training programs in recent decades, Medintim developed [guidelines](#) for health care providers to understand how to check fit of the Caya diaphragm.

Medintim worked with the social marketing organization DKT Nigeria to gain Caya regulatory approval and in July 2020, DKT launched Caya as a new contraceptive method in Nigeria.

DKT Brazil is working on regulatory submission to ANVISA (the Brazilian regulatory authority) and has completed submissions to regulatory agencies in several other South American countries as well.



The Expanding Effective Contraceptive Options (EECO) project – a USAID-funded project that supports the introduction of new contraceptive options– introduced Caya as a user-initiated nonhormonal method in Niger. This project, implemented by [WCG Cares](#) and PSI, compared acceptability and uptake through public and private sector clinics in Niamey. A [project brief](#) from this introduction activity was recently released in English and French. Based on the positive response to Caya introduction in Niger, the EECO project is planning for a second introduction activity in Benin.

INTERNAL/FEMALE CONDOM UPDATES

Nel A, Malherbe M, van Niekerk N, Beksinska M, Greener R, Smit J, Freziers R, Walsh T. [Performance and Acceptability of the FC2 Female Condom When Used With and Without a Silicone Placebo Vaginal Ring-A Randomized, Crossover Trial.](#) *Journal of acquired immune deficiency syndromes.* 2020 Sep 1;85(1):58.

Background: The silicone Dapivirine Vaginal Ring 25 mg, has been developed to provide an additional HIV prevention option for women. If approved for use, women will always be counselled to use condoms when using the vaginal ring for maximum protection. This paper evaluates the compatibility of female condoms with the ring.

Methods: This was a 2-period crossover, randomized noninferiority trial. Couples in 2 sites in the United States of America were randomized to FC2 Female Condom (FC2) with and without a placebo silicone ring and asked to use 4 female condoms in each period. The primary noninferiority endpoint was the clinical failure rate during intercourse or withdrawal (self-reported clinical breakage, slippage, misdirection, and invagination). Frequencies and percentages were calculated for each failure mode and differences in performance of the 2 periods, using the female condom without the ring as reference. Noninferiority was defined using an 8% margin at the 5% significance level. Safety and tolerability were also assessed.

Results: Eighty-one couples were enrolled and 79 completed the trial using a total of 596 female condoms (297 and 299 with/without a ring inserted, respectively). Total female condom clinical failure was 14.1% and 15.7% in the presence and absence of a ring, respectively, with a difference of -2.1% (95% confidence interval: -7.8% to 3.6%), thereby demonstrating noninferiority when used with the ring. There were no differences in safety and tolerability between the 2 periods.

Discussion: Concurrent use of the placebo silicone vaginal ring had no significant effect on female condom functionality or safety outcomes.



Beksinska M, Wong R, Smit J. [Male and female condoms: Their key role in pregnancy and STI/HIV prevention.](#) *Best Practice & Research Clinical Obstetrics & Gynaecology.* 2020 Jul;66:55-67.

Abstract: Male and female condoms are the only available Multipurpose Prevention Technologies (MPTs) that can prevent unintended pregnancy and sexually transmitted infections including HIV. If used correctly and consistently, condoms can provide levels of pregnancy protection similar to many hormonal methods.

Condoms remain one of the most common methods used at first sexual intercourse and are relied on as a current use of contraception by adolescents in many regions of the world. Male and female condoms are safe and require no prescription; in particular male condoms are generally easy to access at low cost. Female condoms are more expensive than male condoms and less accessible; however, they have the advantage of being a female-initiated method. Condom users may experience some common challenges; however, recent advances in condom technology have led to new designs and modifications of existing products to improve quality and make them more attractive, acceptable and pleasurable for consumers and increase its use.

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, internal/female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information

For more information, contact Laura Fix, CBAS Executive Director, at info@cervicalbarriers.org.

CBAS is coordinated by Ibis Reproductive Health.



www.ibisreproductivehealth.org