Regulatory Approval Opens the Way for European Launch of New Single-Size Contraceptive Diaphragm

PATH

The device is safe, comfortable, and easy to use, expanding nonhormonal contraceptive options for women

Soon, women in Europe may be taking a new look at one of the world's oldest forms of contraception. European regulators have granted the single-size SILCS Diaphragm a CE marking, allowing the product to be sold throughout Europe. The launch is also an important step toward expanding nonhormonal contraception options for women worldwide.

SILCS is the first new cervical barrier method to receive regulatory approval and enter the market in more than a decade. It was designed through a unique collaboration between PATH, a Seattle, Washington-based global health nonprofit; CONRAD, a reproductive health product development organization operated through the Eastern Virginia Medical School in Norfolk, Virginia; the United States Agency for International Development (USAID); and other partners. In 2010, PATH licensed the SILCS design to Kessel Marketing & Vertriebs GmbH (Kessel), a private-sector company in Frankfurt, Germany, to accelerate women's access to the technology.

This June, Kessel will launch SILCS in six European countries. The product, marketed as the Caya™ contoured diaphragm and sold through health providers and pharmacies, will later be expanded to additional markets.

"PATH has more than 35 years of expertise developing and introducing new and overlooked approaches to global health challenges, so we knew that a well-designed and marketed diaphragm could have real health benefits for women worldwide," said Steve Davis, president and CEO of PATH. "This multiyear process has taken the persistence and dedication of a remarkable group of public- and

private-sector partners. Our work is by no means over, but this launch moves us one step closer to expanding women's options for contraception."

Worldwide, many women who don't want to become pregnant aren't using existing contraceptive methods for a number of reasons, including concerns about the side effects of hormonal contraception; wanting a method that can be used only when they need protection; or finding it difficult to negotiate condom use with their partners. Often, women have difficulty reaching a health care provider to discuss, initiate, or maintain other methods. The SILCS Diaphragm could help address the needs of these women.

Women and their partners in the Dominican Republic, South Africa, Thailand, and the United States validated the design of SILCS through user acceptability studies. CONRAD validated the safety, acceptability, and effectiveness of SILCS in clinical studies for safety and effectiveness. "[Our] pivotal study showed that the SILCS Diaphragm used with contraceptive gel is as effective as the traditional diaphragm used with contraceptive gel," said Marianne Callahan, deputy director of clinical research at CONRAD. "The advantage of SILCS is that women do not need a pelvic exam to determine their diaphragm size, which can be an obstacle to access. Studies also show that this single-size device fits most women." CONRAD has a long history of collaborating with organizations like PATH to create new methods of contraception and HIV prevention for women.

Together, these improved features have the potential to make SILCS a valuable option not only in Europe but for the estimated 222 million women worldwide [1] who still have an unmet need for modern family planning. Introducing the method in developed countries, where traditional diaphragms are still available as part of family planning programs, will inform future introduction in low-resource settings where diaphragms have not been available in recent decades. A single-size device, rather than a diaphragm that comes in multiple sizes, will be easier to supply and provide.

These efforts, and continuing work to expand SILCS, have been funded primarily by USAID. "This woman-initiated, nonhormonal contraceptive barrier method has great potential to improve women's reproductive health options by addressing several of the reasons for unmet contraceptive need," said Judy Manning, team lead for contraceptive research and development at the agency. Manning added that the device may fill another needed role by "serving as a delivery method for gels that help protect against HIV and other sexually transmitted infections—it could be our first true multipurpose prevention product."

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. "It is vitally important to expand access in the United States to methods that improve women's pregnancy and STI prevention options," said Wayne C. Shields, president and CEO at the Association of Reproductive Health Professionals (ARHP). "ARHP supports the availability of as many safe, effective prevention options as possible, since each woman's sexual and reproductive health needs are unique and vary over her life span."

PATH and its research partners in Uganda, India, and South Africa are also gathering information on opportunities and challenges for introducing SILCS in low-resource settings. Marleen Temmerman, director of the Department of Reproductive Health and Research at the World Health Organization (WHO), noted the promise of these efforts: “The SILCS barrier method has the potential to avert health outcomes from unintended pregnancies, particularly for women in resource-poor settings, and will form part of the WHO’s strong commitment to achieving universal access to reproductive health through expanding choice and method mix.”

The European regulatory approval and launch announced this week mark important progress toward these goals.

For more information, visit www.path.org [2].

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