

Contraceptive Device Discovered to Have Broad Spectrum Application for Women's Basic Unmet Needs

Shihata Alfred^{1*} and Brody Steven A²

¹MD Scripps Institution of Medicine and Science San Diego, CA, USA

²MD, PhD, Director of Life Span Medical Institute San Diego, CA, USA

*Corresponding author

Shihata Alfred, MD Scripps Institution of Medicine and Science San Diego, 14058 Mira Montana Drive, Del Mar CA 92014, CA, USA

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Abstract

Introduction: The FemCap is an FDA, and CE mark approved barrier contraceptive device. To our surprise, it was found to apply to several basic unmet reproductive health needs for women. a) The FemCap is time tested hormone-free contraceptive device, b) It offers an alternative delivery system to the traditional vaginal applicator, c) It provides a safe and effective non-surgical treatment for stress urinary incontinence (SUI), d) It enhances the fertility awareness methods.

Methodology: We conducted several pilot studies to explore the potential of the FemCap. We compared the retention and distribution of stained vaginal gel if inserted with the FemCap versus the same amount of gel when inserted by the vaginal applicator. We compared the safety and effectiveness of the FemCap with a vaginal pessary that treats stress urinary incontinence. We collected the fertile cervical mucous (Spinnbarkeit) with the FemCap to determine the time of ovulation to enhance the fertility awareness method.

Results: The FemCap is a well-established, safe, and effective non-hormonal contraceptive. The retention and distribution of stained vaginal gel inserted with the FemCap is more efficient than the vaginal applicator. The FemCap's unique storage groove for microbicides can potentially be utilized to treat sexually transmitted infections (STIs) topically. FemCap is also found to be substantially equivalent to the incontinence pessary in controlling stress urinary incontinence (SUI). The FemCap did also help to collect fertile cervical mucous (Spinnbarkeit) when using fertility awareness methods.

Conclusion: The multipurpose FemCap would be an ideal tool for nurse practitioners, midwives, and physicians to provide women with safe and effective, hormone-free contraception. It also provides an efficient delivery system for spermicide/microbicides. It is much safer for non-surgical management of stress urinary incontinence. It is useful for the enhancement of fertility awareness methods. It is non-invasive and can be inserted and removed by the woman without professional help.

Keywords: FemCap, Delivery system, non-hormonal contraception, Stress urinary incontinence, Fertility awareness methods

The FemCap Early Development

The FemCap was developed in response to the HIV/AIDS epidemic. The FemCap was designed with a unique deep groove facing the vaginal opening (Figure 2-4) [1].

This groove was intended to store the spermicide/microbicide and traps the sperm, bacteria, and viruses upon deposition into the vagina, while keeping the spermicide from touching the cervix to minimize any possible irritation. The cervix was determined to be

the main primary portal of entry for HIV when transmitted from men to women. This is due Not Only to open Os but also to the presence of chemokine co-receptors for HIV on the cervix, called CCR5 and CXR4. These receptors must be present for HIV to enter the CD4 cell for its destination. **HIV+CCR5+ CXR4 +CD4 cell = AIDS infection.**

An initial concern with the first-generation FemCap was that be too difficult for women to place the FemCap over a tilted cervix

correctly. To remedy this, we designed an applicator to place the FemCap correctly. Actual data showed that women did not have trouble placing the FemCap over the cervix even if tilted (Figure 1). However, they did have difficulty in removing it. Since the insertion was not an issue, the applicator became obsolete.

The Virus must first fuse with these receptors before they enter the CD4 cells. The unique FemCap groove is designed to trap sperm bacteria and viruses upon deposition into the vagina and expose them to microbicides for a prolonged period (Figure 4)[1].



Figure 1: FemCap 1st Generation FemCap (obsolete)



Figure 3: FemCap Views

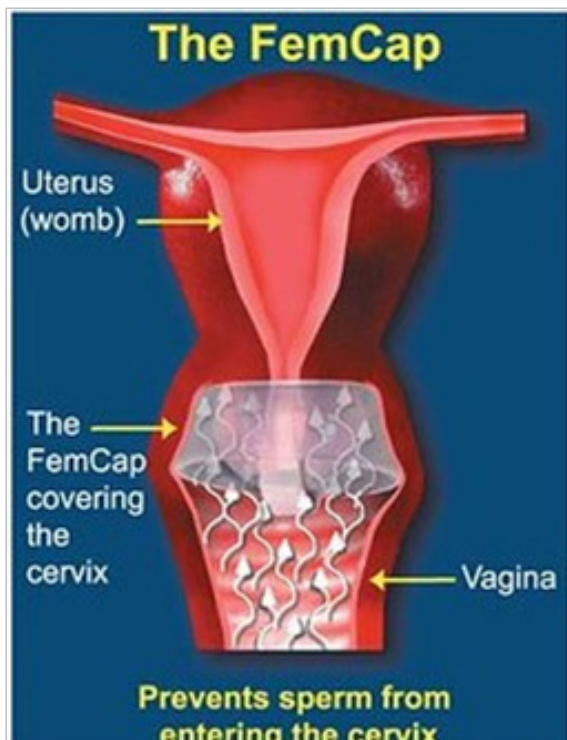


Figure 2: FemCap 2nd Generation FemCap (current)

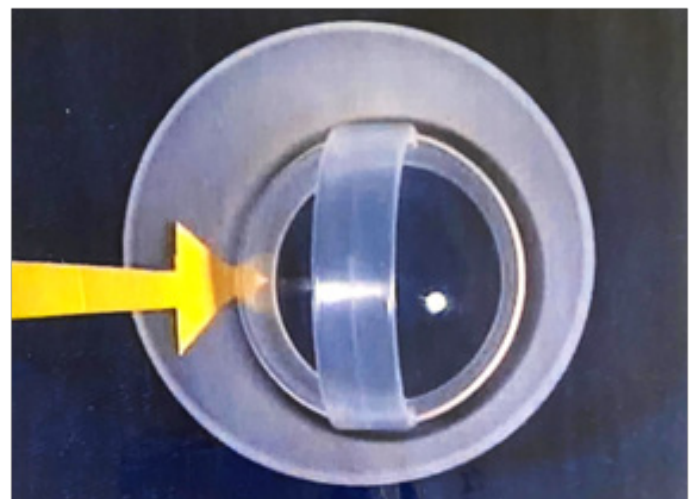


Figure 4: FemCap's delivery system

Contraceptive Device

The introduction of the FemCap to the market was timely as there were limited options for hormone-free birth- control methods. The FDA and the European countries approved the FemCap for contraception and denied its approval for HIV/AIDS for ethical and logistic reasons.

Vaginal applicators have been used for centuries to deliver ther-

apeutic creams into the vagina. Unfortunately, the bulk of these therapeutic vaginal creams are expelled by the rhythmic contraction of the vagina and thus rendered less effective with a waste of money and delay of diagnosis. Women urgently need an alternative to the inefficient vaginal applicator, delivery system of proper diagnosis and treatment.

Stress Urinary Incontinence (SUI) is very prevalent among women of all ages, particularly menopausal women. SUI is underreported by women, as well as underdiagnosed and under-treated by health care professionals.

Fertility Awareness Methods are the safest and the most cost-effective contraceptive options, yet they are the least prescribed by doctors and least used by women.

Background

1. FemCap as a Contraceptive

It is well established that the male condom is the only device that can prevent both pregnancy and sexually transmitted diseases (STDs). However, the condom is not well accepted by either partner and thus may not be used properly or used at all, by people at higher risk for STDs. The Following table is a comparison between the male condom and the FemCap.

In medieval times, European women used half a lemon to cover

er their cervix to prevent pregnancy. This modality is the closest to the current cervical cap, while the rind of the lemon act as a mechanical barrier and the lemon juice act as a spermicide. Prentif-cavity-rim cervical cap was invented in 1838 and currently is obsolete (Figure 5).



Figure 5: Prentif Cap-rim cervical cap

The diaphragm is much larger than the FemCap and designed to cover the entire pelvis, from the Posterior fornix to the Symphysis pubis. The diaphragm is designed like a cup with disregard to the anatomy (Figure 6,7). It is made of rubber and stainless-steel spring in the rim to keep its rounded shape. This is versus the anatomically designed FemCap that is much smaller than the diaphragm and covers only the cervix (Figures 8-13) [3-9].



Figure 6: Diaphragm

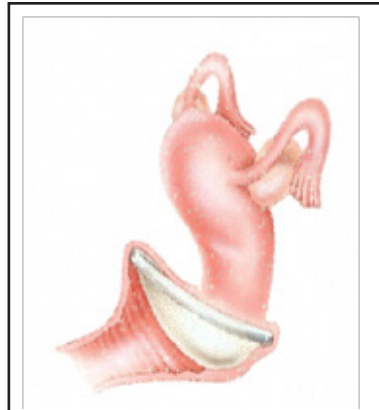


Figure 7: The Diaphragm displayed into the pelvis



Figure 10: FemCap lateral view



Figure 8: FemCap Covering Cervix

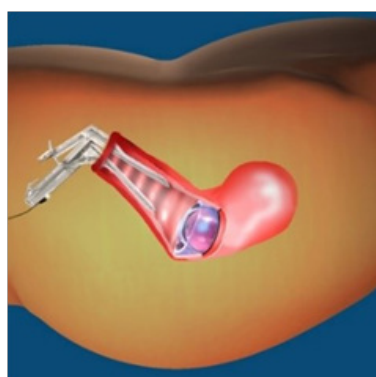


Figure 9: FemCap Speculum View

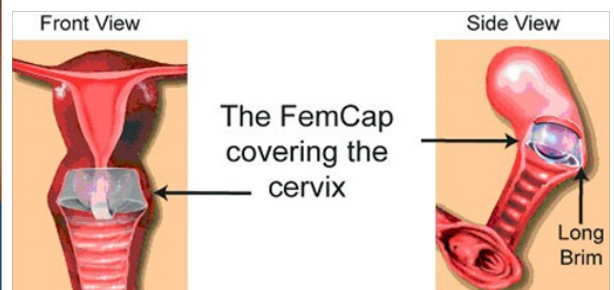


Figure 11: FemCap Over Cervix



Figure 12: Second Generation FemCap

The brim of the FemCap flares outwards against the inwards contraction of the vagina, causing the brim of the FemCap to adhere and conform to vaginal walls creating a tight seal without causing any undue pressure over the vagina or urethra (Figure 2, 8). This contrasts with the rigid rim of the diaphragm that kinks the urethra, that may cause partial obstruction of urination and increased incidence of urinary tract infection.

The FemCap is designed with a unique groove facing the vaginal opening (Figure 2, 4). This groove acts as a trap for sperm and storage for spermicide or future microbicide versus the diaphragm, where the spermicide is applied over the ball, facing the cervix, which can disrupt and damage the delicate single layer of the endocervical canal cells.

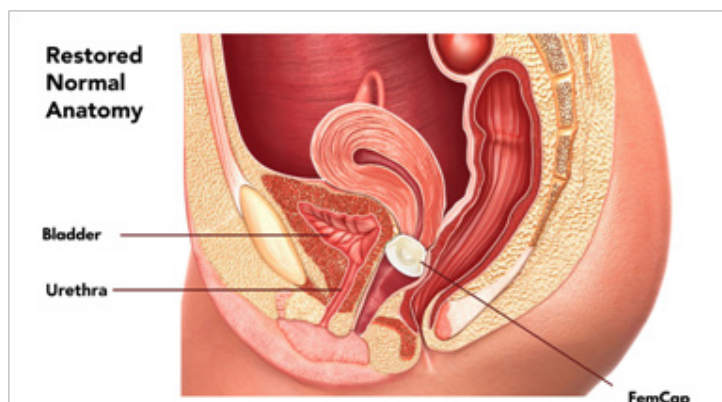


Figure 13: FemCap in Place

The FemCap is designed with a removal strap across the dome, eliminating the potential fingernail abrasion during removal. Compared to the diaphragm, where a fingernail abrasion can occur during removal (Figure 7, 12).

FemCap Size selection depends on the obstetrical history without the need of laborious fitting needed for the several sizes of the diaphragm.

The FemCap offers protection for 48 hours Versus the Diaphragm that is not recommended for any longer than 24 hours.

Table: Comparison Between the Male Condom and the FemCap

	The Male Condom	The Fem Cap
Gender Control	Male-controlled	100% percent woman-controlled and can be applied without the knowledge of the man.
Spontaneity of intercourse	The condom interrupts the spontaneity of intercourse to both partners, which may lead to inconsistent use.	The FemCap does not interrupt spontaneity as it should be applied before sexual arousal.
Sexual sensations	It reduces the pleasurable sensations of intercourse to both males and females.	It doesnot reduce sensation to either partner.
Acceptability	It is not well accepted by either partner particularly the male.	It is universally accepted by both males and females.
User's failure and timing of application	Men rush to apply the condom to avoid the loss of erection. They may apply it incorrectly or may not even apply it at all, during the heat of the passion (poor timing).	Once the woman learns how to apply the Fem-Cap it will become an easy routine with minimal chance for user's failure.The woman can apply the FemCap at any time of her choosing when she is not rushed.
Break age and leakage	The condom can leak and break even if it is used consistently and properly.	Is made of durable material that is impossible-to leak or break during usual use.
Allergic reaction	Most male condomsare made of latex, which can cause allergic reaction.	Is made of an inert non-allergenic silicone material.

Storage and shelf life	Latex material deteriorates very quickly if it is not stored properly particularly in hot tropical-countries.	Is made of durable material that can withstand extremes of temperature without any deterioration.
Cost	Costs \$.90 - \$1.00 for a single use, which translates to \$108-\$120 per year assuming it is used 3 times a week for 40 weeks per year of use.	It comes with an instructional online DVD and Costs \$89, and it is reusable for more than one year.
Hazard to the environment	May pose environmental hazard if not properly disposed	Does not pose any environmental hazard.

2. FemCap as a Delivery System

Some women in the western world, self-diagnose and treat their vaginal discharge by antifungal preparations. They waste hundreds of millions of dollars, pollute the environment, and delay their proper diagnosis. Most of these women misdiagnose any vaginal discharge as a yeast infection and treat it with over-the-counter

antifungal cream. A fair percentage of these women have a normal discharge, and some may have Bacterial Vaginosis, or sexually transmitted infections yet all are self-treated by the same over the counter antifungal preparations using the traditional applicator (Figure 14).



Figure 14: Traditional Vaginal Applicator



Figure 15: FemCap's Delivery System

The advantages of topical treatment of localized vaginal and cervical infections are as follows:

- We can use a smaller dose that would be more effective than a larger systemic dose with less side effects
- Avoid oral digestive enzymes that may degrade the medication or bypass the liver's metabolism
- Under the control of the user
- Does not interfere with intercourse

Vaginal applicators have been used for centuries to deliver creams and gels into the vagina. The physiologic, rhythmic contraction of the vagina expels the menstrual fluid and cervical secretions quickly, as well as any therapeutic vaginal creams (Figure 14). Vaginitis and cervicitis are usually treated by vaginal creams delivered with the vaginal applicator or systemic drugs that come with side effects. The few infections that are treated topically by gels or creams that are inserted by vaginal applicator. Unfortunately, the vagina expels the bulk of these gels or creams shortly after insertion, rendering them less effective.

3. FemCap for SUI

A current FemCap user tipped us off that the FemCap can be used for, stress urinary incontinence (SUI). She said that the days she was using the FemCap for contraception she noticed that her stress incontinence was resolved. Armed with these observations, we conducted a pilot study to explore the validity of this observations. The surprise result was sixteen women out of 19 were completely dry when used the FemCap [2].

Currently available pessaries have significant limitations such as displacement, erosion or even ulceration and urethral obstruction. (Figure 16) [17-20].



Figure 16: Pessaries for SUI

The FemCap shows marked similarity to the ring pessary (Figure 4, 16, 17). The Rim of the FemCap is similar in shape and function to the ring pessary that supports the bladder neck. The outward flaring brim restores the anatomy of the urethra and the vagina. The bowl of the FemCap supports the cervix and prevents it from prolapsing, which provides further support. We conducted a pilot clinical trial to check the feasibility of the FemCap in controlling stress urinary incontinence. The surprise result was sixteen women out of 19 were completely dry [21].

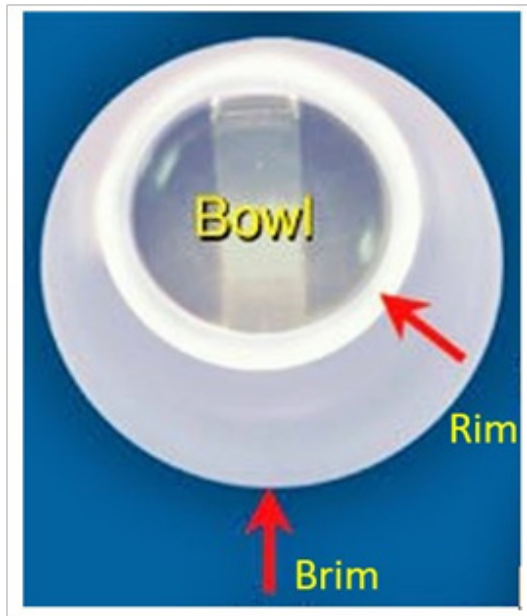


Figure 17: FemCap Brim & Rim

4. The Fertility Awareness Method is the safest and the most cost-effective of all contraceptives, yet it is the least prescribed by doctors and the least used by women. We attribute this to the fact that women miss the most important sign of ovulation during their fertile window (Figure 19), which is the fertile cervical mucus (Spinnbarkeit) (Figure 19) [8-15]. The FemCap allows women to collect a high-quality sample of their fertile cervical mucus directly from the source. The FemCap also prevents the fertile cervical mucus from mixing with other vaginal secretions [8].



Figure 18: Ring Pessary

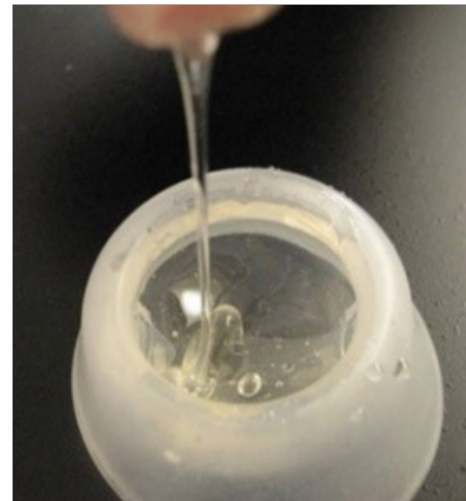


Figure 19: Fertile cervical mucous (spinnbarkeit) collected by the FemCap

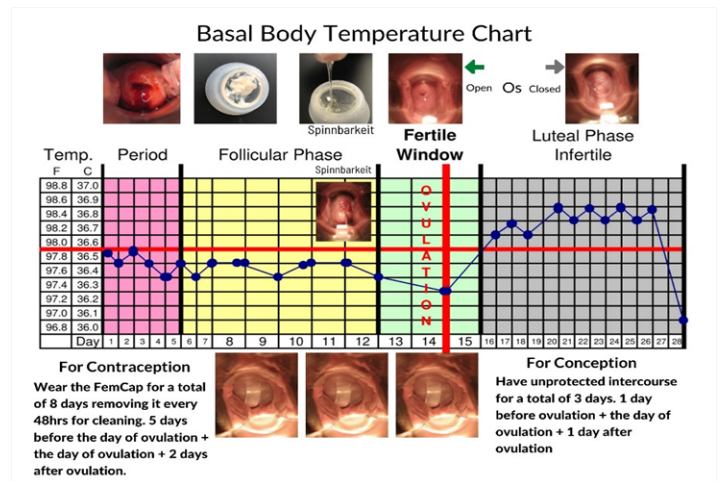


Figure 20: Basal Body Temperature Chart

Methodology

- The FemCap was originally designed in response to HIV [1]. AIDS epidemic Protecting the Cervix mechanically and chemically was found to be the most effective way to prevent the transmission of HIV from men to women. The FemCap was designed with a unique groove facing the vaginal opening designed specifically to serve several objectives, one being to store desired gel to protect against sexually transmitted diseases, including HIV (Figure 4). The storage groove minimizes the leakage of any gel, which is a prevalent problem with the diaphragm. Also, to protect the fragile endocervical columnar epithelial. The bulk of gel that causes the leakage would be stored in the groove facing the vaginal opening, not the cervix. This ensures that sperm bacteria and viruses, are exposed to microbicide or spermicide upon deposition into the vagina. Historically, the diaphragm and the Prentif-cavity rim cervical cap, were the only non-hormonal contraceptives available for women. When hormonal methods were introduced, cervical barriers such as the Prentif-cavity-rim cervical Cap became

obsolete. Hormonal contraceptives are easy to use; however, they have many undesirable side effects. Women are becoming more aware of the adverse effects of hormonal contraceptives. In response to the global awareness of severe hormonal side effects, there is a noticeable increase in demand for safer, more natural methods of contraception for women. The safety and efficacy of non-hormonal barrier methods inspired the author to invent the FemCap. We conducted a critical review of the available barrier methods to overcome drawbacks and improve upon the design. To develop an ergonomic device that conforms and adapts to the physiological changes in the vagina, we considered the cervical and vaginal anatomy. We changed the material used to produce these devices from Latex to a hypoallergenic, durable, medical-grade silicone. Participants selected for this study were ages 18 to 40 years, not pregnant, and did not desire to be pregnant during the 4-week study duration. All subjects were free from sexually transmitted infections and reported being sexually active. Thirty participants (75% of whom were sterilized and 25% of whom were on hormonal contraception), signed an informed consent and underwent a complete physical and pelvic exam as well

as pap smear and wet mount. Women who have had a STI, vaginitis or abnormal pap smear were excluded.

- Twenty women (Group A) were randomly assigned to use the vaginal applicator, (Figure 14) and the other 20 women (Group B) were assigned to use the FemCap to deliver the same high viscosity vaginal lubricant stained with Gentian violet dye, to enhance its visibility. Participants were instructed to record and report the use of the vaginal applicator and the FemCap and any side effects on a calendar (Figure 22). This facilitated a comparison between and compliance with the vaginal applicator to deliver a vaginal lubricant stained with Gentian violet and with the FemCap to deliver the same stained lubricant. We swabbed each participant's vagina and introitus for the presence or absence of the stained lubricant at 12, and 24 hours after insertion of the lubricant using both devices. In addition, we photographed the cervix at 12 and 24 hours. Finally, the investigators conducted in-depth interviews with each of these 40 women to gain more insight for our goal to treat vaginitis and possibly STIs topically in the future.



Figure 21: Applicator users had no Stain on the cervix after 12 hours

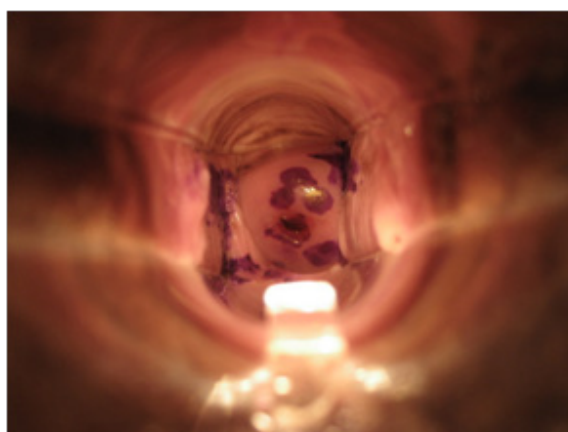


Figure 22: FemCap users had Stain on the cervix after 24 hours

- A woman who was using the FemCap for contraception reported to me that she was also suffering from Stress Urinary Incontinence (SUI). She reported that the days she used the FemCap for contraception she did not have any episode of stress incontinence. This led me to investigate the use of the FemCap as a SUI pessary (Figure 17-19). Stress Urinary Incontinence (SUI) is very prevalent among women of all ages, particularly menopausal women. SUI is under-reported by women as well as under-diagnosed and under-treated by doctors. The first line of SUI treatment is pelvic floor muscle (Kegel) exercises and vaginal pessaries. The ring pessary is most widely used however, more pessaries of different shapes and sizes (Figure 16) have been introduced into the market with the hope of achieving better results.
- We previously conducted a pilot study using the FemCap which allowed women to see the distinction of the mucus. It

resembles clear raw egg-white and stretches about 2-3 inches before it breaks. This is the most important sign in identifying ovulation and the fertile window with astonishing precision. This methodology shortened the fertile window to 3 days for conception and 8 days for contraception. This simple non-invasive and low-cost method can maximize the chance of conception or contraception in healthy women having regular periods. It should be noted that the efficacy of this method depends intensively on user motivation, compliance, and accurate, and consistent recording. The use of the FemCap to collect the cervical mucous at its source can pinpoint the day of ovulation and thereby enhance Fertility Awareness methods [22, 23].

Summary

The intravaginal non-hormonal contraceptive devices available are extremely limited, and women need safe and effective alter-

natives that correlate with their lifestyle. Non-hormonal options are especially important for women who have contraindications or aversion to hormones or IUDs. The FemCap is a multipurpose device that functions in three major areas of unmet women's health. The unique sailor hat design conforms to the cervical anatomy and prevents pregnancy by blocking the sperms' access to the cervix. Ensuring the device is easy to use was a main factor in development. FemCap requires minimal one-on-one training from a health care professional, and the user has full control.

Because it sits directly at the cervix, it is a great tool to collect cervical mucus used to pinpoint ovulation with the fertility awareness method. Recently, it was discovered that the FemCap will also help manage Stress Urinary Incontinence. It would be ideal and cost-effective for women to acquire one multipurpose device that can be used for contraception, to control stress incontinence, and enhance fertility awareness methods.

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