

Bringing to market their FemCap Hormone-Free Contraceptive and their FemmyCycle® Menstrual Cup, FemCap, Incorporated is focused on Improving the Quality of Reproductive Health for Women



Dr. Alfred Shihata CEO

BIO:

Dr. Shihata is President and CEO of FemCap, Inc. and the inventor of the FDA-approved FemCap and FemmyCycle devices. He has dedicated the last 30 years of his career to research in women's reproductive health, focusing his attention on hormone-free contraception and sexually transmitted disease prevention. Dr. Shihata holds six United States patents and eight international patents. He is a life member of the Society of American Inventors, the European Society of Contraception and the Association of Reproductive Health Professionals.

He has authored several articles published in national and international journals and made a number of presentations on his research in the U.S. and abroad. He developed the Fem-Cap, one of the safest FDA-approved methods of contraception, and the cost-effective, eco-friendly Femmy-Cycle menstrual collection cup.

He has received the Gold Medal Award from World Wide Patents, and more recently, BIOCOM honored the FemmyCycle with the prestigious *Why Didn't I Think of That?* Award. This distinction is given to "the device that meets a blatant unmet need in an elegantly simplistic and obvious way". BIOCOM judge Lorie Shoemaker said of the FemmyCycle, "It's a game changer. It's simple, it's safe, it saves money, it saves the planet, and it can save your life." The FemCap was also nominated for the Prix Galien 2009 Award.

> Healthcare Medical Device



About FemCap, Incorporated:

FemCap, Incorporated is a female reproductive device company focused on fulfilling reproductive health needs in a way that benefits women and the environment. FemCap, Inc. manufactures two devices:

1) The FemCap: an FDA-approved silicone contraceptive device that is a safe and effective alternative to hormonal contraceptives such as the pill,

the patch, or IUDs, and the condoms. It is hormone-free, has no side effects, and does not interfere with sexual desire or pleasure to either partner or breastfeeding. It is also designed to deliver antimicrobial and antiviral drugs to the cervix and the vagina to provide targeted treatment for and/or protection from Gonorrhea, Chlamydia, Trichomoniasis, yeast, HPV and HIV, and other STIs.

2) The FemmyCycle®: The Femmy-Cycle is an innovative, FDA-approved menstrual cup that is safe, ecofriendly and cost effective. It is a soft medical grade silicone device that prevents the mess and leakage associated with almost all other feminine sanitary products. Because the FemmyCycle collects blood rather than absorbs it, the risk of toxic shock syndrome is eliminated, even when worn for 10-12 hours. It is reusable for 1-2 years, making it an environmentally sound alternative to pads and tampons that end up in landfills.

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Dr. Shihata, would you please tell us a little bit about Fem-Cap, Incorporated?

Dr. Shihata: FemCap, Incorporated is a medical device company that manufactures and markets two FDAapproved devices. The first is the FemCap, which is a hormone-free contraceptive for women who cannot or do not wish to use hormones. The second device is a menstrual collection cup. Instead of women using pads and tampons, it is a collection cup that is inserted into the vagina,

and women cannot feel it at all while it is in place. It collects the menstrual flow with a unique "no spill" design that is almost leak free. Both devices are intended to bridge the gap between what women need and what is available to them in the reproductive health market. Large pharmaceutical companies are interested in multibillion dollar drugs such as birth control pills, but they do not manufacture little niche devices like this. Therefore, I try to fill the gap by producing these two much needed devices that are safe for women and safe for the environment.

CEOCFO: Both of them seem like more than a niche device! It seems to me that you could have a big market for both. Would you tell us about the FemCap? What is it made out of? How and why does it work? Why has this not been done before?

Dr. Shihata: Good questions. The

material is inert silicone rubber, the purest silicone. The human body cannot recognize its presence. It is made in three sizes, to be able to fit almost any woman. The small size is for women who have never been pregnant. The medium size is for women who have had a miscarriage or cesarean section, or in

other words, who have not had a vaginal delivery. The larger size is for women who have had a full-term, vaginal delivery.

CEOCFO: Is it in use now?

Dr. Shihata: It is available all over the world. It is actually the only cervical cap available anywhere in the world. It is available in North America, Europe—all the European countries and is being shipped to Australia, New Zealand, everywhere. It is the only cervical cap approved all over the world.

CEOCFO: How do people find out about FemCap?

Dr. Shihata: Good question. I am a medical doctor by trade, so I do not know very much about marketing. I am a scientist, so I have spent thirty years in research and development in

women's reproductive health. I do not advertise. You have probably noticed that I do not advertise. The only thing I have is the website and word of mouth. That is it. That is how people find out about it. I get increased, repeated sales, all the time.

CEOCFO: Is it in stores?

Dr. Shihata: It is not in the stores. However, it is in certain pharmacies. The FemCap is an FDA-approved device that prevents pregnancy prevents a condition—you need a prescription for that sort of device.

CEOCFO: What do you hear from women?

Dr. Shihata: They love it! If you go on the website you will find some testimonials. I receive feedback from many women who love it.

CEOCFO: What is the comfort level of FemmyCycle?

"FemCap, Inc. manufactures Hormone-free contraceptive, the FemCap and the FemmyCycle menstrual cup. Both devices are eco-friendly, cost-effective, and safer for women and the environment. If there is one thing I want people to know about FemCap as a company, it is that the FemCap and the FemmyCycle are both designed specifically to improve the quality of reproductive health for women."- Dr. Alfred Shihata

> Dr. Shihata: It is so comfortable that women do not even perceive its presence. Women cannot feel it at all. The human vagina does not have sensory somatic nerves. For example, your finger has sensory somatic nerves. If I ask you to close your eyes and I give you a coin you can tell me if it is a quarter, a dime or a nickel. The vagina does not have this sensation. It only has autonomic sensations. For example, women have been wearing tampons since 1940. They like them despite all of the drawbacks of tampons, because they cannot feel them. The most sensitive part of the vagina is the outer part: the vulva, the labia, and labia minora (inner labia). But once the FemmyCycle is inside the vagina, the woman cannot perceive the presence of the device. A diaphragm is huge and has a wire in it, yet ninety nine percent of women

cannot even feel it. Some women use a pessary. That is a device for women with urinary incontinence. Pessaries are made of very strong, heavy metal covered by rubber that would hold the cervix, uterus and bladder higher up on top of the pelvic bone, so bladder would not leak. Even the pessary cannot be felt in the vagina. Women cannot feel the FemmyCycle at all. It is like it does not exist.

CEOCFO: How often do you need to take it out during your menstrual cycle?

Dr. Shihata: We just measure the average woman's menstrual flow for twelve hours. For hygienic reasons, though, it is good to frequently change it. Women can use it up to twelve hours. However, some women have a very heavy menstrual flow. These women might use it for eight hours or less, depending on the flow.

CEOCFO: Is FemmyCycle sold over the counter?

Dr. Shihata: Yes. This is over the counter. It is considered to be like pads and tampons. It is not considered a prescription device. This is due to the fact that it does not treat any condition or diagnose or prevent any disease. I just received FDA approval for the Fem-

myCycle two months ago, on November 15, but it is for sale now in Europe and in the United States. But the FemCap is a prescription device, because it prevents conception. You need a prescription for it.

CEOCFO: What is the plan for the next six months, the next year? What will you be doing to get the word out, to move along?

Dr. Shihata: I have several plans. One of them is an "exit strategy". I am getting on in years, and I work about sixteen hours a day; about fourteen hours when I have a slow day. Therefore, I am looking for an exit strategy, I would want to sell FemCap, Inc. to a good company that would not "bury" my products, but take them to the next level. This company, if they have the right marketing, could generate millions of dollars through the Fem-

Cap and the FemmvCvcle. I did some very limited marketing research, and I found out that women in Europe and the United States spend thirteen point four billion dollars a year on pads and tampons. All of these pads and tampons go into landfills and pollute the environment. Sometimes, they even pollute the sub-ground water. So currently. I am marketing these products in countries where the environment is of particular concern. Women in third world countries are still using rags, believe it or not. They use rags for their periods, and every woman that I talk to dreads her period and dreads that time. It is very inconvenient.

CEOCFO: How will you find what you need?

Dr. Shihata: In fact, I am sitting still and people are finding me. I do not want to sound arrogant, but it is true. For example, how did you find out about me? I did not call you. You called me. That is how all of my clients find me. They call me. I do not call them. It is a great product with a great demand among women from all walks of life. I am here in San Diego close to the Mexican border. When we show the FemmyCycle to Mexican women who lack access to education and have a limited understanding of their own anatomy, all we tell them is "fold this and insert to collect your menstrual flow. Pull it down and dump the flow in the toilet, and wash it and use it again." They understand and want to try the product.

CEOCFO: Why should investors and people in the business community be paying attention to FemCap?

Dr. Shihata: Great demand by the vast majority of women for our products. The FemCap is for women who are health conscious. They do not want any hormones or chemicals to go into their bodies. You asked me how the FemCap works. It is very simple. It stops the sperm from getting inside the uterus, period. It is a sperm blocker. Many, many women suffer silently from birth control pills and hormones that have serious side including heart attacks, effects. strokes, and even death, among young women. This is all from using hormones. Many women do not suffer heart attack or stroke, but they do suffer from minor side effects, like gaining weight. Most women hate the weight gain. Then there's bloating, soreness of the breast, and psychiatric problems as well. They feel depressed on the pill or the hormones. And most recent studies show that women on hormones loose the desire for sex. That is because the birth control pill fools the women's body into feeling as if she is pregnant. When a woman is pregnant, the hormone for pregnancy decreases her desire for sex. There are many side effects. The FemmyCycle also has tremendous potential in the women's reproductive health market. Feminine sanitary products are a multi-billion dollar industry, and the FemmyCycle represents the first significant advance within that industry in many decades.

CEOCFO: What should people remember most when they read the story of the company, FemCap? **Dr. Shihata:** The FemCap and the FemmyCycle are for health conscious women who either cannot do not want to put hormones or chemicals into their bodies. These products are safer for women and for the environment. They protect the environment from pollution and protect women from side effects. The FemCap has been available on the market for the last twelve years. There has not been a single side effect that was reported to the FDA or anyone. That is because if a woman does not like it, she can remove it and throw it away. It is not imbedded in her body liked a hormone shot or the IUD. She cannot remove a hormone shot for three months. If she has a side effect, it is in her system. The FemCap is a sperm blocker that does not introduce any chemicals into the woman's body. It does not produce any side effects. If there is one thing I want people to know about FemCap as a company, it is that the FemCap and the Femmy-Cycle are both designed specifically to improve the quality of reproductive health for women. The FemCap is hormone-free and is safer for woman and safer for the environment. Also, it is very cost effective. For example; if a woman buys a FemCap she will not need another one for a year or two. If she buys a FemmyCycle she will not need another one for a year or two. If she goes to the store and buys birth control every month-that is several hundred dollars. If she goes and buys pads and tampons, it is more than one hundred dollars a year. Our products are designed to save money, time, hassle, and the environment. That is what I would like people to remember.



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