

Enhancing your opportunity to conceive... the Cap is Key ... because getting pregnant involves more than timing.

Frequently Asked Questions

Q: What is the Conception Kit[™]?

A: The Conception Kit[™] is a safe, effective, easy-to-use, affordable, private method to help increase the chance of becoming pregnant. It is approved by the FDA and the European Community, has been granted U.S. Patent #5857959, and is ISO 13485: 2003 certified for quality.

The most important part of the Conception Kit^{TM} is the Conception Cap – a small silicone device not much bigger than a thimble that is filled with semen and placed on the cervix for six to eight hours. Inserting the Conception Cap is painless and simple.

By holding the semen at the opening of the cervix for up to eight hours, the Conception Cap gives the sperm an enhanced opportunity to pass into the uterus and fertilize the egg. Although the technology has been around since the 1950s, the Conception Cap is the first such device that can be used effectively by women in the privacy of their own homes.

The Conception Kit[™] contains a three-month supply of Conception Caps, ovulation predictors, pregnancy test kits, non-latex semen collectors, sperm friendly intimate moisturizer samples, multi-lingual timing wheels, a journal, and a medical provider note card/envelope. The Conception Kit[™] comes with full instructions.

Q: What's the need for the Conception Kit[™]?

A: About one in six women experience difficulty becoming pregnant. According to the U.S. Dept of Health and Human Services, about 6.1 million American women between the ages of 15 and 44 have an impaired ability to have children. About nine million women in the U.S. have used infertility services.

Until the Conception Kit[™], there has been no safe, effective, easy-to-use, affordable, private method for increasing the chances of becoming pregnant. Only clinical infertility services are as effective: most of them start at \$500 for a one-time intracervical injection to beyond \$18,000 for a one-time *in vitro* fertilization (IVF) procedure, which most health insurance policies do not cover. The Conception Kit[™], on the other hand, costs only \$459 for a three-month supply.

Q: What causes of infertility does the Conception Cap help overcome?

A: According to the American Society of Reproductive Medicine, about one-third of infertility cases can be attributed to male factors, one-third to factors affecting women, and the remainder are caused by a combination of problems in both, or are unexplained.

The Conception Kit[™] can help address the following male-related problems:

- Low sperm motility (weak swimming sperm)
- Low sperm count
- Irregular position of the penis opening (hypospadias and epispadias)

The Conception Kit[™] can help address the following female-related problems:

- Timing of ovulation
- Hostile vaginal environment
- Position during intercourse
- Tilted cervix

When sperm are concentrated in the Conception Cap, they do not have to contend with such issues as:

- Making the long journey through the vaginal cavity to the cervix
- Being pulled out of the vaginal cavity by the penis
- Becoming lost in the vagina
- Being flushed out by gravity
- Being met by a hostile vaginal environment, or
- Semen not pooling in the right location to meet up with the cervix

Q: What infertility issues does the Conception Kit[™] <u>not</u> address?

- A: The Conception Kit[™] cannot overcome the following infertility issues:
 - Endometriosis
 - Azzospermic (no sperm in the semen)
 - Scarred uterus
 - Blocked fallopian tube
 - Luteal phase defect
 - Polycystic ovary syndrome
 - Low follicle stimulating hormone
 - Genital warts
 - Polyps and fibroids
 - Age
 - Other serious conditions

Q: What is the success rate of the Conception Cap?

A: A study conducted in 1996 in the United Kingdom¹ found that use of a cervical cap was nearly as effective as intracervical injection in the treatment of infertility.

¹ University of Bristol Department of Obstetrics and Gynecology, St. Michael's Hospital. C. Cousin, E.R.

McLaughlin, S. Harris, M.C. Ford and M.G.R. Hill. Findings published in Human Reproduction, vol. 11 no. 1 pp. 84-87, 1996.

A second study, conducted in 2000² by The Jones Institute of Norfolk, Virginia, also found that use of a cervical cap was nearly as effective as intracervical injection (IV) in the treatment of infertility. The Conception Cap was tested by The Jones Institute for its effects on the following factors:

- Sperm motility
- Sperm/cervical mucus penetration
- Sperm/egg binding
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The Jones Institute's study concluded that the Conception Cap did not adversely affect any of these three factors. The results of the clinical trial were submitted to the FDA as part of Conceivex's application.

- **Q:** What are the advantages of the Conception Kit^{M} over other infertility treatments?
- A: Affordability, ease of use and privacy.
- Q: Cervical cap technology has been used for conception since the 1950s. What's different about the Conceivex Conception Cap?
- A: Early conception cap devices were made from surgical steel and had to be inserted by a physician, after which the woman had to lie with her hips elevated for four to six hours in the doctor's office.

By contrast, the Conception Cap is made from medical grade silicone and can be easily and painlessly inserted by the woman herself in the privacy of her own home. She does not have to lie down once the cap is in place.

Q: Who designed the Conception Cap?

A: Michael La Vean designed and patented the Conception Cap. La Vean has a long, successful history in reproductive health care. In 1999 he was awarded the Gynecological Innovation of the Year Award in both France and Italy for the development of the Oves brand of over-the-counter <u>contraceptive</u> cervical cap.

La Vean soon saw a need for a safe and effective product to help couples having difficulty conceiving a baby. It occurred to him that a cervical cap designed specially for <u>conception</u> was needed. Determined to help couples realize their family goals, La Vean started Conceivex, Inc. Today, Conceivex manufactures the Conception Cap and the Conception Kit[™].

Q: Will my doctor be okay with my using it? Should I let him/her know first?

A: Yes, women should let their physician know that they are trying to conceive using the Conception Kit[™].

² The Jones Institute for Reproductive Medicine, Department of Obstetrics and Gynecology, Eastern Virginia Medical School, Norfolk, Virginia. Findings published by Mahoney, M.C. Evaluation of the effect of a cervical cap device on sperm functional characteristics in vitro. Andrologia, 33, 207-213 (2001).

Inside every Conception Kit[™] is a medical provider note. This pre-printed note should be sent to your doctor or health care professional prior to using the Conception Kit[™], informing them that you are trying to become pregnant.

If you do not let your health care professional know you are trying to become pregnant, they might prescribe drugs that could interfere with conception. For example, antihistamines can dry up the mucus found at the opening of the cervix; the cervical mucus plays a very important role in helping the sperm swim through to the uterus.

Q: Does the Conception Cap come in different sizes? How do I know which size I need? Does it need to be professionally sized or fitted?

A: The Conception Cap's patented design allows it to fit virtually all women who have never delivered a baby, and most women who have delivered a baby. The three side flanges inside the Conception Cap accommodate a variety of cervical diameters.

Q: Can the Conception Cap be used with fertility medications?

A: Yes.

Q: How long does the Conception Cap need to stay in place?

A: Once it is filled with semen, the Conception Cap should stay in place for six to eight hours, or overnight.

Q: Can a man or woman with a latex allergy use the Conception Kit[™]?

A: Yes. The Conception Cap is made of surgical grade silicone; it contains no latex.

Q: Where is the Conception Kit[™] made?

A: The Conception Kit[™] is made in the United States. The Saint-Gobain facility in Beaverton, Michigan, manufactures the Conception Cap. The Conception Kit[™] is assembled by Liquidpak in Alma, Michigan.

Q: How long after sex should the Conception Cap be inserted?

A: Sperm can live up to one hour outside the human body. After the semen has been collected in the semen collector during sex, we recommend that it be transferred into the Conception Cap and placed on the cervix as soon as possible.

Q: Does the conception cap increase the chances of multiple births like some other infertility tools?

A: No. The Conception Cap simply moves semen closer to the egg. Unlike some other infertility treatments, the Conception Cap does nothing to alter the egg or the sperm.

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