



## Conception Kit™ Background

The Conception Kit™ is a safe, effective and affordable method to help women overcome infertility in the privacy of their own homes.

The key element in the Conception Kit™ is the Conception Cap, a patented, 21<sup>st</sup> century upgrade of the highly effective cap insemination methodology. The Cap is made from the same implantable-grade silicone approved by the FDA for such medical devices as heart valves, artificial arteries, artificial joints and pacemaker covers. Once it is filled with semen and put on the cervix, where it remains for up to eight hours, this device gives the sperm a significantly enhanced opportunity to pass into the uterus and to fertilize the egg. Placing the Conception Cap is painless and simple.

Both the Conception Kit™ and Conception Cap have been approved by the U.S. Food & Drug Administration and granted Marking (Conformité Européene) authorization by the European Union.

The Conception Cap and Conception Kit™ were developed by Michael La Veau™, a Michigan inventor with a long history in reproductive health care. In 1999, La Veau's first company was awarded the Gynecological Innovation of the Year Award in both France and Italy for his invention of Oves, the over-the-counter contraceptive cervical cap.

Aware that roughly one in six women of child-bearing age – about 6.1 million American women<sup>1</sup> – has difficulty becoming pregnant, La Veau took his expertise to invent a cervical cap specifically for *conception*. He founded Conceivex, Inc., in 2004 to manufacture and distribute the Conception Cap and Conception Kit™. These two reproductive tools are designed to be used in conjunction with each other to enhance a couple's opportunity to conceive.

### **The Conception Kit™ can help overcome such infertility issues as<sup>1</sup>:**

- Low sperm motility
- Low sperm count
- Tilted cervix
- Timing of ovulation
- Hostile vaginal environment

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<sup>1</sup> Source: U.S. Dept of Health & Human Services

**The Conception Kit™ is not designed to overcome the following infertility issues:**

- Endometriosis
- Azospermic (no sperm in the semen)
- Age
- Scarred uterus
- Blocked fallopian tube
- Luteal phase defect
- Polycystic ovary syndrome
- Low follicle stimulating hormone
- Genital warts
- Polyps and fibroids
- Other serious conditions

The Conception Kit™ is unique in several important ways. Most critical is the design of the Cap: no other over-the-counter product places the semen/sperm at the opening of the cervix (cervical os) for as long as eight hours during the “window of opportunity” when ovulation has most likely occurred. Second, the Kit contains a three month supply of all components needed for a couple to maximize the Conception Cap’s effectiveness – three Conception Caps; three non-latex semen collectors; 24 ovulation predictors; conception timing wheels (one English & one French/ Spanish); three pregnancy test kits; medical provider note and envelope; instruction manual; and a journal to record progress. Three samples of sperm-friendly intimate moisturizer for comfort during sex have been included.

Because of its safety, effectiveness, ease of use, affordability and privacy, the Conception Kit™ is a very desirable first step for couples who are experiencing infertility. A study conducted in 2000<sup>2</sup> found that use of a cervical cap was nearly as effective as intracervical injection (IV) in the treatment of infertility. Priced at \$459 for a three-month supply, the Conception Kit™ can serve as an option for couples wishing to explore alternate methods prior to more expensive and invasive clinical procedures costing as much as \$18,000 per *in vitro* fertilization attempt. Most health insurance policies do not cover *in vitro* fertilization and other costly procedures.

Conceivex sells the Conception Kit™ over the Internet, [www.conceptionkit.com](http://www.conceptionkit.com), in order to keep the product as affordable as possible. The Conception Kit™ and Conception Cap are made in the United States under ISO 13485: 2003 quality certification standards.

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<sup>2</sup> 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).