

# Frequently Asked Questions

## Has the product been evaluated by the FDA?

Yes, the Stork OTC received FDA over-the-counter clearance in July of 2014 (K140186). The product is available to purchase without a prescription at multiple retailers. For a full list of retailers visit <http://www.storkotc.com/where-to-buy/>

## Where can I purchase the Stork OTC?

The Stork OTC is available to purchase at select retailers online and in-store. For a full list of retailers please visit [www.storkotc.com](http://www.storkotc.com) and click "BUY NOW".

## What is the Stork OTC?

The Stork OTC is a uniquely designed medical device you use at home, during ovulation, to assist your chances of becoming pregnant by using the cervical cap insemination technique. This smart technique enables the sperm to quickly bypass the vaginal tract and places the sperm as close as possible to the opening of the cervix, right where it needs to swim up through to get to the egg. The product can be used in private, at home, without a prescription.

The product includes an innovative applicator and a cervical cap within a condom-like sheath (Conceptacle). The Conceptacle is worn during intercourse to collect the semen into the cervical cap (the device can alternatively be used with donor sperm). The cervical cap is removed from the condom-like sheath, and inserted into the applicator. The applicator is inserted into the vaginal tract and the cervical cap of semen containing sperm is placed at the opening of the cervix. The cap remains in place for up to 6 hours, after which it is removed with a simple tampon-like pull string.

## What is cervical cap insemination?

Historically, cervical caps have been used for conception dating back to the 1950's. The cervical cap keeps the sperm at the opening of the cervix for up to 6 hours. Benefits of cervical cap insemination include:

- Pregnancy success rates of up to 20%, comparable to intrauterine insemination success rates (16-21%).
- Prevention of backflow of semen into the vagina<sup>1</sup>.
- Prolonged exposure of the spermatozoa (Sperm cell) to the cervical mucus<sup>1</sup>.
- Enables sperm to bypass the vaginal environment quickly, reducing the risk of sperm loss in the vaginal tract<sup>1</sup>.
- Considered a less invasive method of aiding in conception with a limited number of risks<sup>2</sup>.

The Stork OTC uses this technique adding a special applicator to improve the delivery method of the cervical cap to the cervical opening.

## Who should use the Stork OTC?

- Couples who are trying to become pregnant.
- Male patients diagnosed with low sperm count or motility issues.
- Couples trying to become pregnant without intercourse.
- Healthy couples who desire to control timing.
- Couples who seek out private options for trying to conceive or at-home insemination options.
- Couples who are not ready to take the next-step to in-clinic treatment options (i.e. IUI, IVF).

<sup>1</sup> "A Prospective, randomized, cross-over comparison of two methods of artificial insemination by donor on the incidence of conception: Intracervical insemination by straw versus cervical cap", Human Reproduction, Vol. 12, no.9 1945-1948, 1997, Flierman, Hendrikus, et al. <sup>2</sup> "Evaluation of the effect of a cervical cap device on sperm functional characteristics in vitro", ANDROLOGIA 33, (2001), M. C. Mahony.

**Is there clinical data on the Stork OTC?**

A post coital study (peer-reviewed and published in Surgical Technology International XXVII) demonstrates on average a 3.23 higher value of sperm concentration at the cervix with the Stork OTC compared to the value of sperm concentration with natural intercourse, for 85% of study participants. The remaining 15% of subjects saw no change in sperm concentration between the Stork OTC and natural intercourse.

**When should I use the Stork OTC? Can I use it anytime during the day, morning, afternoon and evening?**

Suggested use of the Stork OTC is on the three most fertile days of the female partner's cycle. The Stork OTC conception device allows you in the privacy of your home to use the device when it is convenient and most comfortable for you. Please keep in mind, if you are using (1) Stork OTC device, it is best to use right before ovulation. If you are using (3) Stork OTC devices, please use one device on each of your three most fertile days of your monthly cycle. Rinovum recommends tracking your ovulation with an ovulation tracking kit to determine your most fertile days to use the Stork OTC.

**Can we try normal intercourse during/in the same month we are planning on using The Stork OTC?**

Yes, you can have normal intercourse during the same month you are planning on using The Stork OTC. Research studies suggest male sperm count can decrease if there is ejaculation on a daily basis; it is often recommended that couples have intercourse every other day to build up their sperm production between ejaculations.

**How long after placing the cervical cap do I have to wait before returning to normal activities?**

You can return to normal activities immediately after placing the cervical cap and removing the applicator. You should not have sexual intercourse while the cervical cap is inserted, as it may cause discomfort to you or your partner.

**How long should I keep the cervical cap in?**

The cervical cap should remain in place for no more than 6 hours. Do not wear longer than 6 hours. Failure to remove the cervical cap could result in complications, including: obstruction of physiological discharge and menstrual flow from the uterus, pain, abrasion/ulceration, or infection.

**Can I urinate using The Stork OTC?**

Yes, you can urinate while the cervical cap is in place with no adverse effects.

**What are the indications for use?**

The Stork OTC is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received diagnoses of low sperm count, sperm immobility or unfavorable vaginal environment. The Stork OTC contains a cervical cap inside a condom-like sheath. It is used to collect semen into a cervical cap then deliver it to the outside of the cervix as an aid to conception. The Stork OTC should be used during the ovulatory phase of the menstrual cycle. The Stork OTC Cervical Cap should not be left in place for longer than six hours.

**Can The Stork OTC be used while on fertility medications?**

Yes, there are currently no contraindications for the use of fertility medications and cervical cap insemination. However, please speak with your Healthcare Provider regarding taking fertility medications if you plan to use The Stork OTC.

### **Can I use The Stork OTC without using the condom?**

The Stork OTC can be used without the condom, but should not be used with another condom other than the one provided. Please read the instructions leaflet provided with the device for details on how to use without the condom.

### **Can I use a regular condom with the applicator provided?**

Use only the Conceptacle (the condom-like sheath with the cervical cap inside) provided in the Stork OTC packaging. Other condoms may contain latex or spermicide, which could kill sperm and impede your conception chances.

### **Does the Conceptacle® contain latex?**

No, the Conceptacle is made of silicone and does not contain latex.

### **Can the device be reused?**

No, each device is designed for single use only. None of The Stork OTC parts should be reused or shared. Reuse of the device may result in an infection, which may endanger future fertility.

### **What is the Expiration / Shelf Life of the Stork OTC?**

The Shelf Life of the Stork OTC is five years. The expiration date will be printed on the side of The Stork OTC Box.

### **The Cervical Cap was only filled with a small amount semen; will the Stork OTC still work?**

When you press Button #3 on The Stork OTC, a spring-fed push occurs, pushing the semen to your cervix and the cervical cap creates a seal, holding the semen next to your cervix for four-to-six hours. Therefore, any amount of semen would work.

### **Can I use a lubricant or moisturizer with the product?**

If partners wish to use an intimate moisturizer or lubricant, make sure to use a sperm-friendly one. Most intimate lubricants or moisturizers are harmful to sperm.

### **Why does the cervical cap only come in one size?**

The cap was designed for both women who have delivered before and women who have not.

### **How long should I use The Stork OTC before speaking with my Healthcare Provider about other options?**

You should always speak to your Healthcare Provider about any concerns or questions relating to fertility. Three to six months of use on the three most fertile days of the female partner's cycle is the suggested use. After six months of unsuccessful use, speak with your Healthcare Provider about another treatment option.

### **Does The Stork OTC protect against HIV or other sexually transmitted diseases?**

No, The Stork OTC does not protect against HIV or STD's. Do not use semen from a partner who has HIV or other sexually transmitted diseases. To avoid HIV or STD's, DO NOT share The Stork OTC.

## Frequently Asked Questions

---

### **Are there any known complications with or adverse reactions to using the device?**

There are no publications that discuss whether cap usage can cause TSS (toxic shock syndrome). The Instructions for Use instruct the user to remove the cap four to six hours after insertion to reduce the risk of TSS. The risk of Toxic Shock Syndrome (TSS) exists for products like tampons and other vaginal devices. TSS is a rare but serious disease that may cause death. Warning signs of TSS include sudden fever (usually 102° F or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn. If these or other signs of TSS appear, remove the cervical cap at once, and seek medical attention immediately. The Stork OTC is intended to assist you in achieving pregnancy. Pregnancy may involve serious health risks for both you and your unborn child. Consult your Healthcare Professional for possible risks before using The Stork OTC.

### **Are there any health conditions that prevent people from using this device?**

The device is not to be used by those for whom it is medically unsafe to engage in sexual intercourse or to become pregnant.

### **Is there any chance for contamination during packaging?**

The product is non-sterile. To avoid contamination, customers are advised not to open or handle the device until they are ready to use it.

### **How soon can I tell if the Stork OTC worked?**

Implantation occurs after an egg has been fertilized. This takes place, on average, 6 to 12 days after ovulation and fertilization of the egg has occurred however every woman is different. The fertilized egg must travel through the fallopian tubes and into the uterus for implantation. Home pregnancy tests vary in how early they can detect the level of hCG hormone. Most healthcare providers recommend that you wait until you have missed your first period before taking a home pregnancy test; usually about two weeks after conception.

### **If I have any questions regarding fertility issues, who should I contact?**

If you have any questions regarding fertility issues, please contact your Healthcare Provider. Rinovum is unable to provide medical advice on use of The Stork OTC.

### **If I live outside of the United States, can I purchase The Stork OTC and have it shipped to me?**

The Stork OTC is available to purchase and ship within the United States.

For information on how to purchase the product in **Canada**, please visit [www.storkconception.ca](http://www.storkconception.ca) for a list of retailers.

For more information on how to purchase the product in the **United Kingdom**, please visit [www.thestorkconception.co.uk](http://www.thestorkconception.co.uk) for a list of retailers.

For information on how to purchase the product in **Australia**, please visit [www.storkconceptionaid.com.au](http://www.storkconceptionaid.com.au)

### **If I have any issues with using the device, whom do I contact?**

The Stork Ib2C, Inc., A Rinovum Women's Health Company  
300 Oxford Drive, Suite 330 Monroeville, PA 15146  
[support@rinovum.com](mailto:support@rinovum.com) • +1 (412) 200-7996