

HCP Frequently Asked Questions

Has the product been evaluated by the FDA?

Yes, The Stork OTC product received FDA clearance to market in July of 2014. The prescription product, The Stork, received FDA clearance in September of 2012. 510(k) Number: K140186.

What technology does the product compete with or replace?

The Stork OTC is an at-home conception device that combines an innovative applicator and an established conception technique -- cervical cap insemination. The Stork OTC utilizes cervical cap insemination, giving couples the ability to use this technique in the privacy of home, without a prescription.

The Stork OTC can be a first-step treatment option for couples before more invasive procedures are considered; bridging the gap between natural intercourse and costly, in-office treatment options (i.e., IUI or IVF). The Stork OTC collects semen into the cervical cap with a condom-like sheath (the Conceptacle) worn during intercourse (or alternatively, donor sperm can be used with the device). The sperm is then delivered to the opening of the cervix by way of the applicator. The cap remains in place for up to 6 hours, after which it is removed with a simple tampon-like pull chord.

Who should use The Stork OTC?

- The patient population that is trying to become pregnant.
- Male patients diagnosed with low sperm count or motility issues.
- Patients trying to become pregnant without intercourse.
- Patients who desire to control timing.
- Patients who seek out private options for trying to conceive or at-home insemination options.

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.

What is cervical cap insemination?

Historically, cervical caps have been used for both conception and contraception 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 vagina¹.
- Prolonged exposure of the spermatozoa (Sperm cell) to the cervical mucus¹.
- Enables sperm to bypass the vaginal environment quickly, reducing the risk of sperm loss in the vaginal tract¹.
- Considered a less invasive method of aiding in conception with a limited number of risks².

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

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.

¹ "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. ² "Evaluation of the effect of a cervical cap device on sperm functional characteristics in vitro", ANDROLOGIA 33, (2001), M. C. Mahony.

How much is the product?

The Stork OTC is \$79.99 for a single-use kit. We offer discounted pricing for healthcare providers who would like to hold inventory in their office.

Where can patients purchase The Stork OTC?

The Stork OTC is available in the US at select CVS stores and online at www.cvs.com/thestorkotc. For a full list of retailers, please visit www.storkotc.com and click "where to buy".

Why is The Stork OTC not covered by insurance?

Rinovum explored the insurance route before The Stork OTC went to market and found that having The Stork OTC covered by insurance would only complicate and add more steps to patients beginning their fertility treatments. Also most insurance plans do not fully cover infertility treatments, which is why Rinovum strives to keep the cost of The Stork OTC down while making it easily accessible to all patients.

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

There were no complications found during clinical studies. There are no publications that discuss whether cap usage can cause TSS (toxic shock syndrome). The instructions for use instruct the patient to remove the cap four to six hours after insertion to reduce the risk of TSS.

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.

Are there any health conditions that prevent patients from using this device?

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

What is the recommended amount of time that a patient should use The Stork OTC?

Three to six months of use on the female patient's three most fertile days of her cycle. After six months of use, the patient is advised to speak with their healthcare provider about another treatment option.

Can the device be reused?

No, each device is designed for single-use only.

Why is The Stork OTC not reusable?

The Stork OTC was designed to be a single-use device to reduce the risk of infection from multiple uses or improper cleaning and storage by the user. The Stork OTC was cleared by the FDA for single-use and cannot be reused.

Can The Stork OTC be used while on fertility medications?

Yes, there are currently no contraindications for the use of fertility medications with cervical cap insemination.

How long after placing the cervical cap does the patient have to wait before returning to normal activities?

The patient can return to normal activities immediately after placing the cervical cap and removing the applicator. Patients should not have sexual intercourse while the cervical cap is inserted as it may cause discomfort. The patient is instructed to remove the cervical cap four to six hours after placing the cap.

If there is an adverse event, whom do I contact?

Either you or the patient can contact us using the contact information below:

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