THE stork® OTC

Instructions for Use

Manufactured for:
The Stork Ib2C, Inc.
A Rinovum Women's Health Company
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www.storkotc.com

⚠ The Stork® OTC conception system is intended as an aid to conception.

⚠ This device is not intended for contraceptive use.

⚠ Do not use this product if it is medically unsafe for you to engage in sexual intercourse or become pregnant.

⚠ Do not use if you have been diagnosed with any of the following conditions: no sperm in semen (azoospermia), blocked fallopian tubes, known STD's (including active herpes, hepatitis), loss of fallopian tubes due to surgeries, or have had a hysterectomy. Please stop use and consult your healthcare professional if you have any questions regarding use of The Stork OTC.

HSSA ≥ 80% after six hours. This device is non-sterile.

Indication 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 a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Stork® OTC contains a cervical cap inside a condom-like silicone 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.

If you have any questions regarding conception, please consult your healthcare professional.

The Stork® OTC is intended to aid you in the process of becoming pregnant. Specifically, The Stork® OTC uses intravaginal or cervical cap insemination. The cervical cap is used to place the semen specimen near the cervical os (the passage between the vaginal cavity and the uterus) where it enters and travels through the uterus to the fallopian tubes where fertilization occurs. The Stork® OTC conception system is a product that collects semen and positions it close to the cervical os (the passage between the vaginal cavity and the uterus). Its main component is the Conceptacle®: a device that consists of a cervical cap that is inside of a condom-like sheath. During sexual intercourse, semen is collected and contained using the Conceptacle's condom-like function. Once the semen is collected, the condom-like sheath of the Conceptacle is rolled down and off of the cervical cap that is contained in the bottom of the Conceptacle. The cervical cap contains and delivers the semen to the cervical os. Once the specimen has been collected, the cervical cap is placed into an applicator that cradles and compresses it for ease of tracking through the vagina to the opening of the cervical os. The cervical cap allows the specimen to stay close to the area that it needs to be to swim up through to get to the egg.

*** This device is intended as an aid in conception and does not guarantee pregnancy. The effectiveness of The Stork® OTC for helping couples conceive has not been evaluated in clinical trials.**

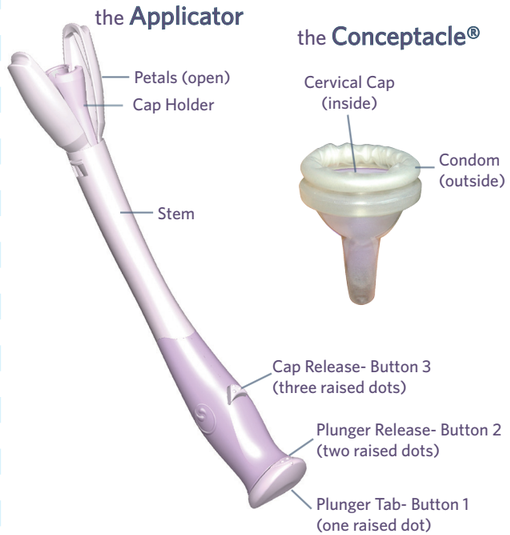
RINOVUM® WOMEN'S HEALTH

Recommendations:
Do not open The Stork® OTC packaging until you are ready to use the device to reduce the risk of system contamination and infection.

When to Use The Stork OTC Conception System?

The device is only for use during the ovulatory phase of the menstrual cycle. Using ovulation predictor monitors will help to determine the most fertile days of the monthly cycle. **The Stork OTC is a single-use device.**

The Stork OTC conception system contains 2 main parts. Familiarize yourselves with the kit:



⚠ WARNING

Read all instructions before use. All safety messages must be obeyed to avoid potential harm.

⚠ WARNING

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 health care professional for possible risks before use of The Stork OTC.

⚠ WARNING

The Stork OTC and its components are **not intended for contraceptive use.** Safety and effectiveness of The Stork OTC for contraception have not been established.

⚠ WARNING

The Stork OTC conception system **will not protect against HIV** or other sexually transmitted diseases. Do not use semen from a partner who has HIV or other sexually transmitted diseases. To avoid HIV or other STDs, do NOT share The Stork OTC.

⚠ WARNING

Do not reuse any of The Stork OTC components. Reuse of the device may result in an infection, which may endanger future fertility.

⚠ WARNING

Remove the cervical cap after 6 hours of wear. 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, and/or infection.

⚠ WARNING

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

⚠ WARNING

Use only the Conceptacle® provided in the system. Do not use regular condoms. Condoms may contain latex or spermicide, which could kill sperm and impede your conception chances.

⚠ WARNING

Do not use this device as a sexual toy. Using this device as a sexual toy could cause discomfort to you or your partner.

⚠ WARNING

To avoid a choking hazard, keep all of The Stork® OTC components out of reach of children.

⚠ WARNING

Stop use and ask a doctor if you experience any discomfort or irritation during or after use of this product.

⚠ WARNING

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 probability of the risk of TSS from the use of cervical caps has not been determined.

⚠ WARNING

If lesions, open sores, viral warts, or other abnormalities are noticeable on either partner, avoid sexual intercourse and consult your healthcare professional.

⚠ WARNING

If you experience any of the following you should consult your healthcare professional:
- If you are not sure about insertion and placement of the cervical cap.
- If you experience any pain or discomfort during this process.
- If, at a time other than during menstruation, upon removal there is blood on the cervical cap.
- If the withdrawal string breaks, retrieve the cervical cap manually.
- If you are unable to remove the cervical cap or any component of the device, contact your healthcare provider.

⚠ WARNING

Do not have sexual intercourse while the cervical cap is inserted into the vaginal tract as this may cause discomfort to you or your partner.

⚠ CAUTION

Do not continue to force the applicator into the vaginal tract if excessive resistance is felt. You may feel slight pressure as the cervical cap meets the cervix, but you should not feel pain or discomfort.

⚠ CAUTION

Always hold the cap upright, touching only the outer surface.

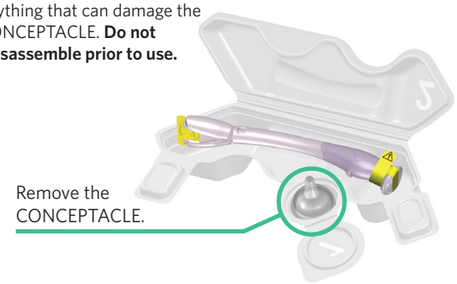
If pregnancy has not resulted after 6 months of trying to become pregnant, consult your physician.

Using The Stork® OTC conception system.
There are 3 steps for semen collection (blue steps 1 through 3) and 4 steps for cap placement (pink steps 1 through 4).

1 Collection★

•Wash hands thoroughly with soap and water.

•Remove the CONCEPTACLE® from package.
Do not use fingernails, teeth, or anything that can damage the CONCEPTACLE. **Do not dissassemble prior to use.**



•Fit the CONCEPTACLE.

•Unroll.

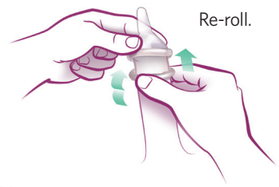
2 Intercourse

•Have intercourse using the CONCEPTACLE.

3 Remove the Cervical Cap from the Conceptacle®

•Wash hands thoroughly with soap and water.

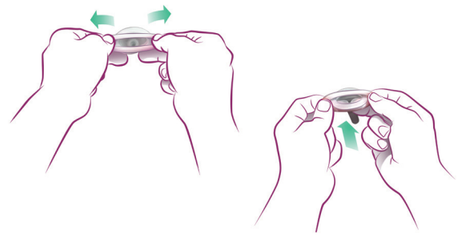
•While still erect, remove the CONCEPTACLE by re-rolling the condom to the CERVICAL CAP.
Re-roll the condom after ejaculation for easier removal.



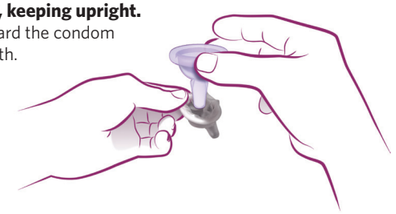
•Separate the CERVICAL CAP by pulling outward on the condom while continually rolling over the outer rim of the CAP.

The CERVICAL CAP is within the condom.

CAUTION:
Always hold the Cap upright, touching only the outer surface.

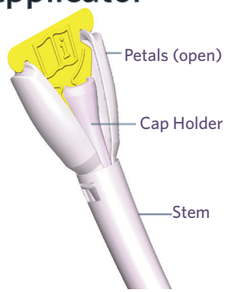


•Extract the CERVICAL CAP, keeping upright.
Discard the condom sheath.



★ When using with donor sperm remove the CERVICAL CAP from condom sheath and add sample to the CERVICAL CAP. Proceed to NEXT PAGE.

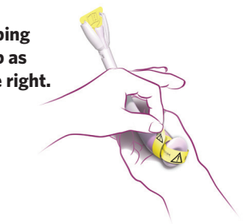
the Applicator



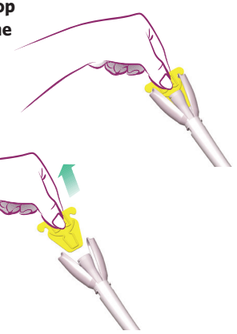
1 Place the Cervical Cap in the Applicator

- **Wash hands thoroughly with soap and water.**

- **Remove the yellow shipping wrap by pulling on the tab as shown in the image to the right.**

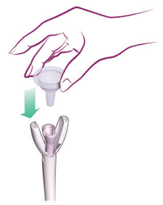


- **Remove the yellow petal spacer by pulling from the top as shown in the images to the right and below.**

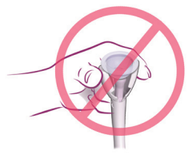


- **Place the CERVICAL CAP onto the open CAP HOLDER, as shown.**

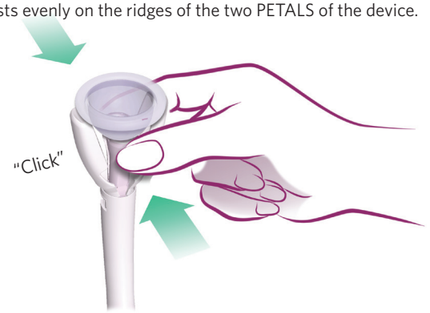
CAUTION:
Always hold the CERVICAL CAP upright, touching only the outer surface.



CAUTION:
Do NOT squeeze the outer PETALS to close the CAP HOLDER.



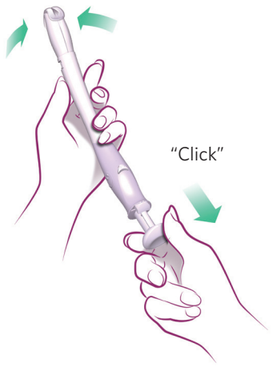
- **Ensure the CERVICAL CAP is in place, then gently squeeze the inner CAP HOLDER closed. You will hear a "click."**
You will know the CAP is in place when the rim of the CAP rests evenly on the ridges of the two PETALS of the device.



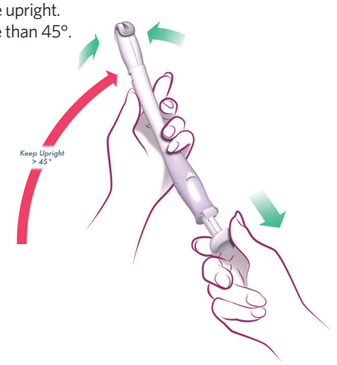
- **Keeping the APPLICATOR upright, pull back on the PLUNGER TAB with the single raised dot (button 1) until the PLUNGER TAB stays back on its own.**

You will feel a slight resistance; hold the Stem firmly, while pulling back on the PLUNGER TAB until you hear a "click."

The CERVICAL CAP will now be pinched closed.

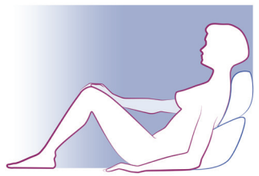


Keep the device upright.
Do not tilt more than 45°.



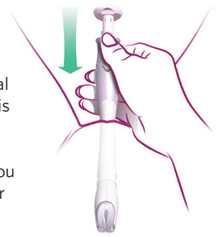
2 Insertion

- **Insertion is best done in a reclining, supine position as shown.** Use pillows for support. Make yourself comfortable.



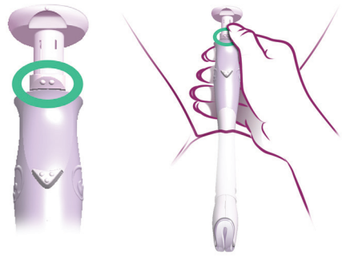
- **Holding the APPLICATOR as shown, introduce it into the vaginal tract, sliding gently until the tip reaches the cervix and you can no longer advance.**

CAUTION:
Do not continue to force the APPLICATOR into the vaginal tract if excessive resistance is felt. You may feel slight pressure as the CERVICAL CAP meets the cervix, but you should not feel discomfort or pain.

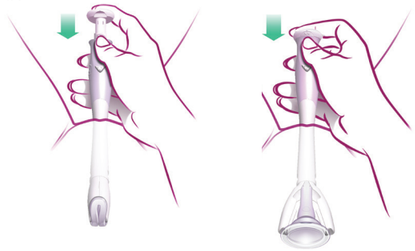


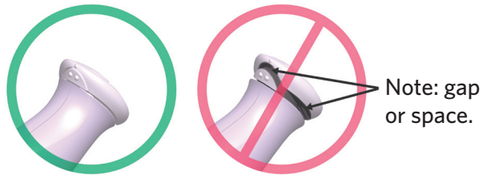
- **Release the PLUNGER by depressing the PLUNGER RELEASE BUTTON with two raised dots (button 2). You will hear a "click."**

"Click"



- **While keeping the APPLICATOR against the cervix, depress the PLUNGER TAB to open the CERVICAL CAP.**
This allows the CAP to be opened but not released at the cervix and also allows you to make final adjustments prior to releasing the CAP.

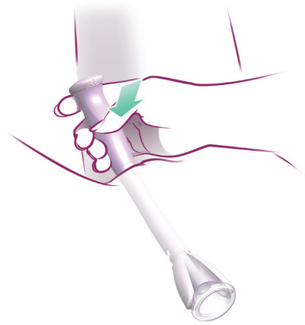




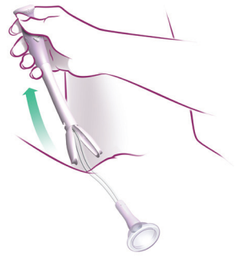
Correct **Incorrect**

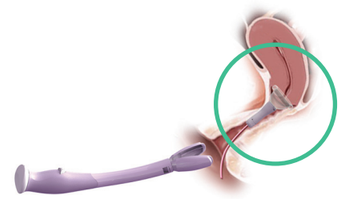
3 Release Cervical Cap

- **Release the CERVICAL CAP by depressing the CAP RELEASE BUTTON with 3-raised dots (button 3).**



- **Remove the APPLICATOR and discard.**
The Removal string is now exposed.





*Placement of the cervical cap on cervix.

The Stork® OTC allows you to continue with normal activities. Do not have intercourse again until after removal of the CERVICAL CAP.

4 Remove the Cervical Cap

- **After 4-6 HOURS, remove and discard the CAP. Do NOT reuse any components.**

STORAGE & USE

STORE BETWEEN:
-22°F (-30°C) – 130°F (54°C)

KEEP DRY

KEEP AWAY FROM SUNLIGHT

Store between -22 to 130°F (-30 to 54°C)

If you do not understand these instructions or if you have any questions, email or write to:

The Stork Ib2C, Inc.
A Rinovum Women's Health Company
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Support@rinovum.com

RINOVUM® WOMEN'S HEALTH

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P/N LBL-0001 R. 6

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