



Manufactured for:
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- The Stork 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.
- This device is non-sterile.

HSSA ≥ 80% after 6 hours.

Indication for Use

The Stork Conception System is intended for home use by couples who are trying to become pregnant and for whom sexual intercourse and pregnancy are safe. Couples that have known fertility issues should consult their healthcare professional to determine if The Stork is appropriate for use. The Stork 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 cervical cap should not be left in place longer than 6 HOURS.

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

The Stork is intended to aid you in the process of becoming pregnant. Specifically, The Stork 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 fertilisation occurs. The Stork 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 swim up through to get to the egg.

***This device is intended as an aid in conception and does not guarantee pregnancy.**

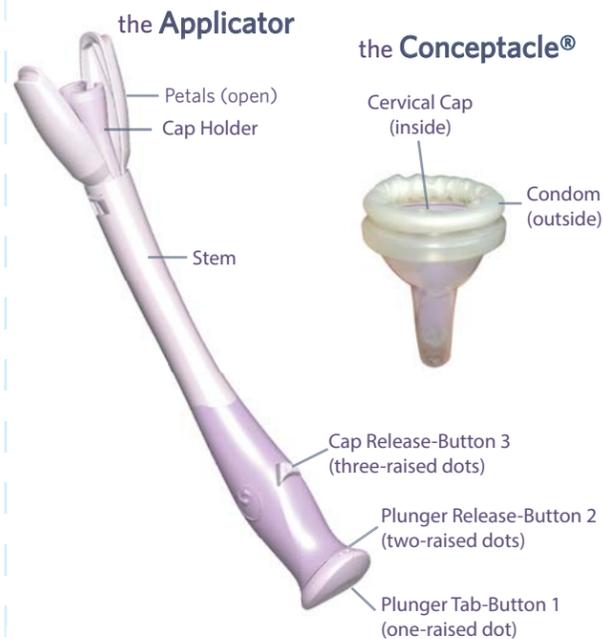


Recommendations:

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

It is recommended that The Stork be used just before and/or during ovulation.

The Stork conception system contains 2 main parts. Familiarise yourselves with the kit.



WARNING

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

- The Stork 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 use of The Stork.
- The Stork and its components are **not intended for contraceptive use**. Safety and effectiveness of The Stork for contraception have not been established.
- The Stork 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.
- Do not reuse any of The Stork components.** Reuse of the device may result in an infection, which may endanger future fertility.
- 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.

If partners wish to use an intimate moisturiser, make sure to use a sperm-friendly one. Most intimate moisturisers are harmful to sperm. Products such as Pre-Seed personal lubricant do not cause harm to sperm.

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.

Do not attempt to use this device for pleasure only. Safety of this device as a sexual toy has not been established.

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

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

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, diarrhoea, 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.

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

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, or you are unable to remove the cervical cap or any component of the device, contact your healthcare professional.

Do not use this device if you have a known silicone allergy.

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.

The Stork is not intended to be used as a menstrual dam. Safety and effectiveness of The Stork as a menstrual dam have not been established.

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.

Using The Stork® Conception System can be done in: 3 steps for the male to collect the semen (blue steps 1 through 3) and 4 steps for the female (pink steps 1 through 4)

1 Collection

•Wash hands thoroughly with soap and water.



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



•Fit CONCEPTACLE.



•Unroll.



Ensure penis is erect.



Ensure proper alignment.

2 Intercourse

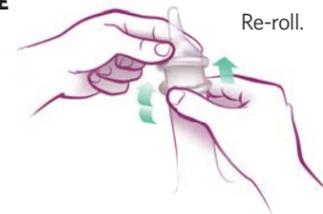
•Have intercourse using the CONCEPTACLE.

3 Remove Cervical Cap from Conceptacle®

•Wash hands thoroughly with soap and water.



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



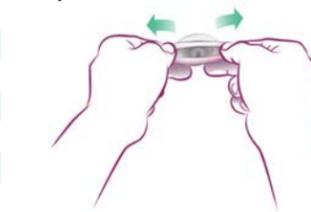
•Separate CERVICAL CAP by pulling outward on condom while continually rolling over outer rim of CAP.

Keep upright.

CERVICAL CAP is within condom.



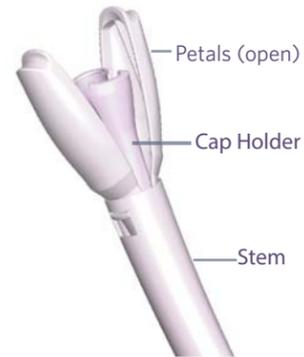
CAUTION: Always hold cap upright, touching only outer surface.



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



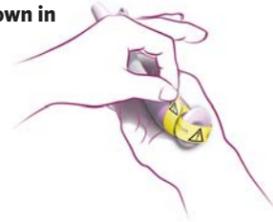
the Applicator



1 Place Cervical Cap in Applicator

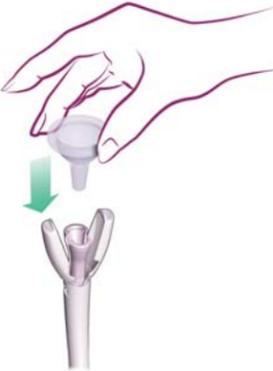
•Wash hands thoroughly with soap and water.

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



•Place CERVICAL CAP onto open CAP HOLDER, as shown.

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



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



•Ensure CERVICAL CAP is in place, then gently squeeze 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.



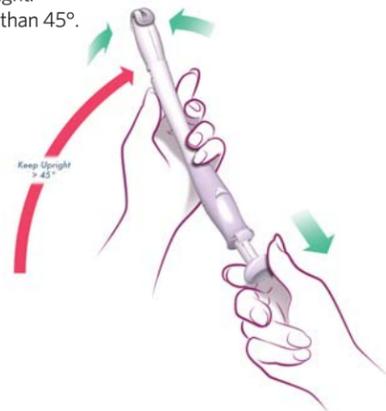
•Keeping APPLICATOR upright, pull back on APPLICATOR'S PLUNGER TAB with the single-raised dot (button 1) until the PLUNGER TAB stays back on its own.

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

CERVICAL CAP will now be pinched closed.

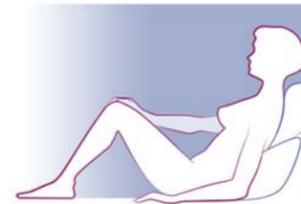


Keep device upright. Do not tilt more than 45°.



2 Insertion

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



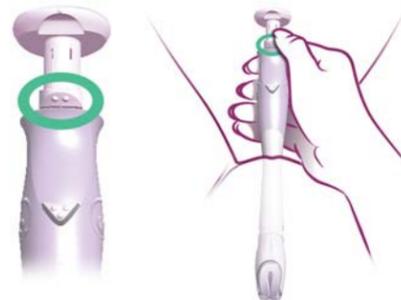
•Holding APPLICATOR as shown, introduce it into the vaginal tract, sliding gently until tip reaches the cervix and you can no longer advance.

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.



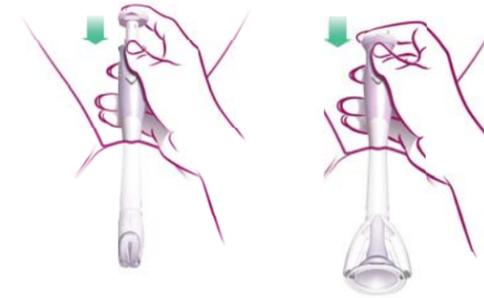
•Release PLUNGER by depressing PLUNGER RELEASE BUTTON with two-raised dots (button 2). You will hear a "click."

"Click"



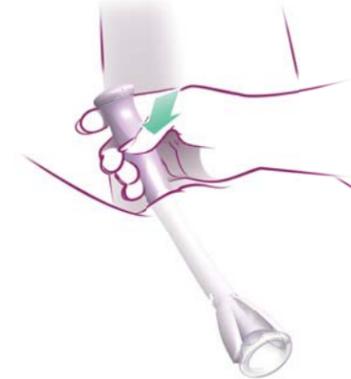
•While keeping APPLICATOR against the cervix, depress PLUNGER TAB to open CERVICAL CAP.

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.

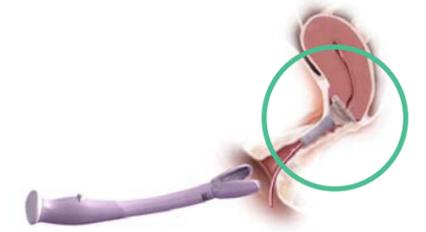
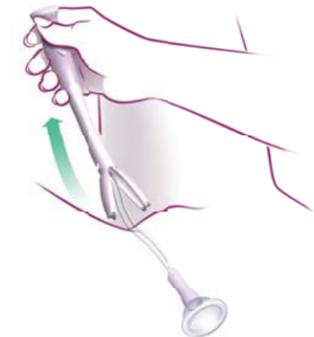


3 Release Cervical Cap

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



•Remove APPLICATOR and discard. Removal string is now exposed.

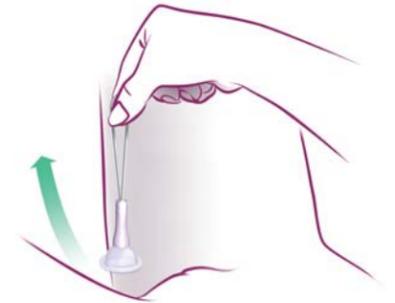


*Placement of cervical cap on cervix

The Stork® allows you to continue with normal activities. Get out of bed and have fun! Do not have intercourse again, until removal of CERVICAL CAP.

4 Remove Cervical Cap

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



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

STORAGE & USE

STORE BETWEEN:

54° C (130° F)

-30° C (-22° F)



KEEP DRY



KEEP AWAY FROM SUNLIGHT

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

If you do not understand these instructions, or if you have any questions, contact Ceuta Healthcare customer services:

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0844 243 666 1

customerservices@ceutahealthcare.com

