

The FemCap™

Female barrier contraceptive

Non-Sterile

Rx Only



The FemCap is recommended to be prescribed by a doctor or nurse.

Patient Information Package

(Please read and retain this information)

Introduction

This package insert is provided to enable you to become familiar with the FemCap and its use. The FemCap is a female barrier device that is intended to prevent pregnancy.

The instructions in this package insert do not replace any more specific instructions that may be recommended by your doctor or nurse.

To understand the risks and benefits of the FemCap, you should read and understand this entire Patient Information Package Insert. If you do not understand any of the material described, ask your doctor or nurse.

The FemCap is designed to prevent sperm from entering the cervix and the uterus (womb). (Fig. 1)

Description

The FemCap is a new female barrier contraceptive device. It is made of silicone rubber, which is durable and easy to clean.

The FemCap is designed to fit your body and allow for changes in your vagina during sexual intercourse.

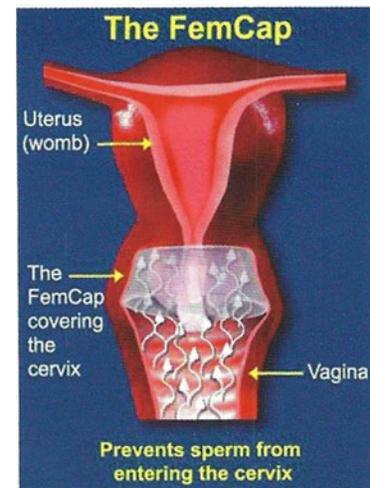
The FemCap comes in three sizes. The inner diameter of the rim determines its size. The smallest rim diameter (22mm) is intended for women who have never been pregnant. The medium (26mm) cap is intended for women who have been pregnant but have not had a vaginal delivery. The largest (30mm) is intended for women who have had a vaginal delivery of a full-term baby.

The FemCap is designed to conform to the anatomy of the vagina to ensure an even distribution of pressure for optimum fit and comfort. The design follows the shape of the cervix and is soft and smooth with no sharp edges.

The FemCap includes a brim, dome, a groove between the dome and brim, a rim, a bowl, and a removal strap. (Fig. 2) The brim serves to form a seal against the vaginal wall and acts as a funnel to direct semen, which contains sperm, into the groove. The groove acts as a reservoir for spermicide and a trap for sperm. The underside of the dome forms a bowl which covers the cervix completely. The strap allows ease of removal.

Insertion and removal of the FemCap are simple and easy to learn in a short time. Once the FemCap is properly placed, it should not interfere with your or your partner's sexual pleasure.

Figure 1



The FemCap was extensively tested and compared with the vaginal diaphragm in multicenter clinical trials in the United States, according to FDA regulations. In these clinical trials 75% of women who had used the diaphragm preferred the FemCap.

Indications for Use

The FemCap is indicated for adult women who desire a barrier device to prevent pregnancy.

Contraindications (Reasons not to use) The FemCap

- ⊗ vaginal/cervical abnormality
- ⊗ allergy to silicone rubber or spermicide
- ⊗ history of Toxic Shock Syndrome (TSS)
- ⊗ if pregnancy poses risk to health or life
- ⊗ gross obesity
- ⊗ inability to insert, position and/or remove the FemCap during menstruation
- ⊗ less than 10 weeks after childbirth, or 6 weeks post-abortion to allow the cervix to return to its normal size.
- ⊗ current cervical or vaginal infection
- ⊗ cancer of the cervix
- ⊗ inability to understand the instructions for use
- ⊗ does not protect against sexually transmitted diseases

Instructions for Use

Caution: Do not insert the FemCap until you have read the removal instructions.

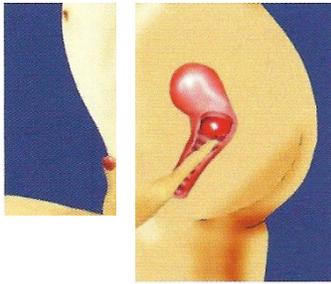
The FemCap must be inserted correctly BEFORE sexual arousal to insure proper placement and to avoid interruption of spontaneity.

You may insert the FemCap from 15 minutes up to 42 hours before sexual arousal.

1. Before Inserting the *FemCap*

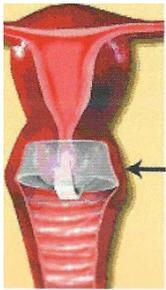
If possible, urinate and empty your bowels. Wash your genital and rectal areas and your hands before inserting the Cap. This will lessen the risk of contamination.

Find your cervix. You must always check the position of your cervix before inserting the *FemCap*. To find your cervix, insert your finger deep into your vagina. The cervix feels like the tip of your nose, and its position varies according to the time of the month and your body position.



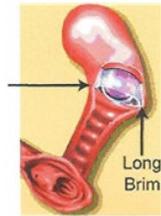
This step is very important because the cervix is your target, and you must know where and how deep you need to place the *FemCap*.

Front View



The *FemCap* covering the cervix

Side View



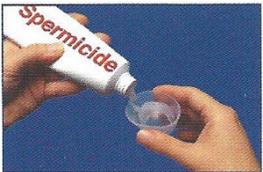
Caution: Do not douche while the *FemCap* is in place. Shower or wash as usual.

2. Inserting the *FemCap*

To prepare the cap for insertion, hold the cap halfway between the long and short brim. Put about **one-quarter** teaspoon of spermicide into the bowl of the cap.



Turn the cap over and put about $\frac{1}{2}$ teaspoon of the spermicide into the groove between the dome and the brim. This groove is designed to hold the spermicide.



Spread the spermicide in a thin layer all over the *FemCap* except for the spots where your finger and thumb are holding the cap (this will prevent the *FemCap* from slipping out of your grasp).



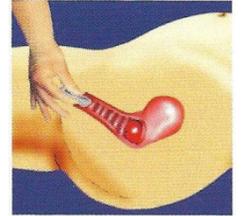
Hold the cap in one hand with the inside of the bowl facing up and the longer brim facing your body. Squeeze your thumb and finger together to flatten the cap.



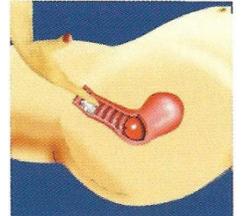
Position yourself in one of these ways: standing with one leg raised on a chair or toilet seat, squatting with both feet on the floor, or lying on your back with both knees bent.



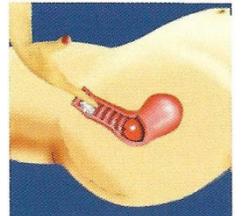
Separate the lips of your vagina with your free hand. Holding the *FemCap* in the squeezed, flattened position with the bowl facing up, insert the cap into your vagina with the long brim entering first.



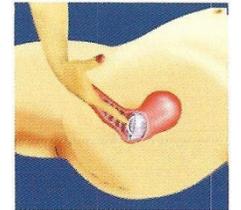
Push the *FemCap* **DOWN** towards the anus,



... and **DOWNWARD BACK** as far as you can ...

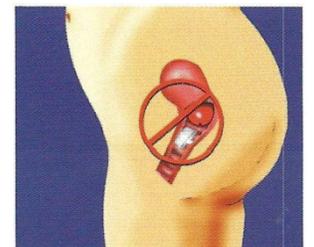


... then push the *FemCap* to cover the cervix completely.



Once the *FemCap* is in place, you may have sex as many times as you wish during the next **42 hours**. You should, however, recheck the position of the *FemCap* and **re-apply about $\frac{1}{2}$ teaspoon of spermicide** before each act of intercourse, **without** removing the *FemCap*.

It is important to avoid placing the *FemCap* partway between your vaginal opening and your cervix. Make sure the *FemCap* is pushed all the way up to cover your cervix completely.



3. To Check Position of the *FemCap*

Check the position of the *FemCap* immediately after insertion, and at least 15 minutes before sexual arousal. This is to ensure that the *FemCap* is placed correctly.

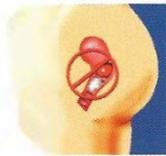
It is best to squat down and then insert your finger into your vagina...



...press upwards on the strap and the dome of the *FemCap* while squatting down. Continue this pressure for at least 10 seconds.



If the *FemCap* is not covering your cervix completely, either push it onto your cervix, or remove it and reinsert it.



4. *FemCap* Removal

Caution: Wait at least six hours after your last act of intercourse before removing the cap. If you remove the *FemCap* sooner, you may increase the chance of pregnancy.

Caution: Be careful not to scratch your vagina with your fingernail while removing the *FemCap*.

To remove the cap, it is best to squat and bear down; as if you are having a bowel movement.

This will bring the cap closer to your finger.



You may rotate the *FemCap* in any direction that is comfortable for you.



Push the tip of your finger against the dome of the *FemCap* to dimple it. This will break the suction and allow room for your finger to fit between the dome and the removal strap.



Hook the removal strap with the tip of your finger.



Finally, gently pull the *FemCap* out of the vagina.



5. Care of the *FemCap*

Wash the cap thoroughly in warm, soapy water and rinse it for the initial use as well as in between uses. Dry the *FemCap* with a soft clean cloth. Do not use heat, synthetic detergents, organic solvents, or sharp objects to clean the *FemCap*.

Keep the *FemCap* in its storage container when not using it.



Replace the *FemCap* every year or sooner if you notice holes, tears, cracks or signs of deterioration.

How Supplied

The *FemCap* is supplied non-sterile and is individually packaged in a reusable plastic storage container in an outer carton. The *FemCap* is provided with a package insert that details information and instructions for use. In addition, an instructional video tape and reusable reference guide are included to assist in the placement and removal of the *FemCap*.

The outer container is marked with the *FemCap* size diameter. The *FemCap* is available in three sizes: 22, 26, and 30 mm, as measured across the inner rim diameter of the bowl. The *FemCap* is also supplied with an identification card that is marked with the cap diameter and manufacturing lot number. This card should be kept in a safe place to allow for identification of the *FemCap*.

Warning and Precautions

To Avoid the Risk of Pregnancy, You Must Use the *FemCap* Correctly Every Time you Have Sex.

If you fail to do so, consult your doctor or nurse, as soon as possible. He or she can provide you with information regarding emergency contraception.

Both insertion and removal of the *FemCap* should be totally painless. If you experience any pain or irritation, or if you have any questions, please consult your doctor or nurse.

The *FemCap* has not been shown to prevent the transmission of HIV, the virus that causes AIDS. A condom should always be used if there is a risk that HIV/AIDS may be transmitted.

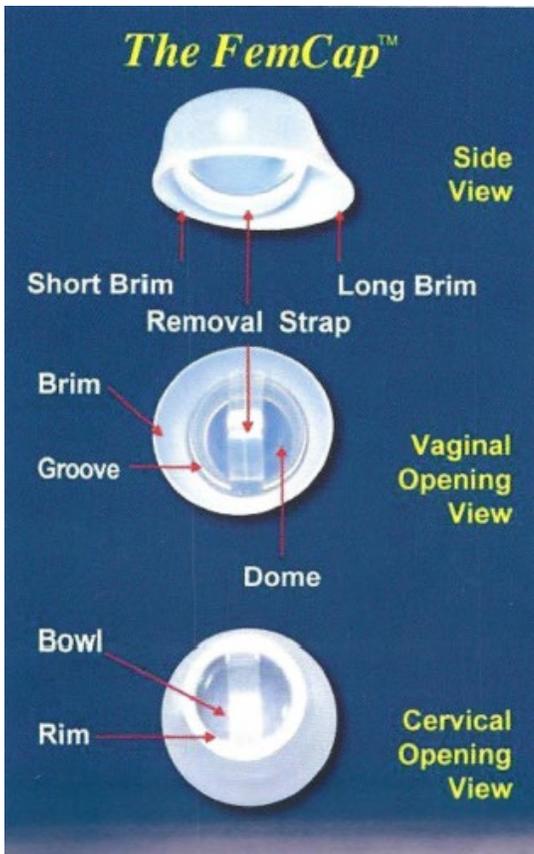
Do not use the *FemCap* during your period. If you do have sex during your period, you should use a condom.

If you ever notice a bad odor while the *FemCap* is in place, or if the *FemCap* has a bad odor upon removal, contact your doctor or nurse.

Although the *FemCap* has never been found to cause Toxic Shock Syndrome (T.S.S.), to avoid the remote possibility of T.S.S., never use the *FemCap* during menstruation, and do not leave it inside the vagina longer than 48 hours.

Symptoms of T.S.S. include: sudden fever (102 ° or more), vomiting, diarrhea, dizziness, muscle aches, or a rash that looks like a sunburn. If you have any of these symptoms, remove your *FemCap* and consult your doctor immediately.

How to Use The *FemCap*™



The *FemCap* is user-dependent and a higher rate of success may be achieved if you:

- A. Use the *FemCap* correctly **EVERY TIME** you have sex.
 - B. Apply spermicide with each act of intercourse.
 - C. If you gain experience with the use of the *FemCap*.
 - D. Use emergency contraception as a backup.
- III. The risk of developing urinary tract infection (U.T.I) while using the *FemCap* was found to be far less than the risk to women who used the diaphragm during the clinical trials. Symptoms of U.T.I. may include frequent and/or burning urination, blood in the urine, and pain in the lower abdomen.
- IV. Potential adverse effects of the *FemCap* may include vaginal infection, abrasion of the vagina or cervix, or an allergic reaction to the *FemCap* material or spermicide.

Possible Problems and What to Do

Consult your doctor or nurse if any of the following occur:

- Difficulty inserting or removing the *FemCap*.
- Uncertainty about proper placement.
- The *FemCap* becomes easily dislodged during inter-course or when you walk, cough, strain or have a bowel movement.
- If, at times other than the onset of menstruation or ovulation, blood is noticed in the *FemCap*.
- If pain or discomfort is experienced by you or your partner during the use of the *FemCap*.
- If you notice unusual vaginal discharge or odor.

Routine Follow-up Examinations

- For an examination and refitting of the *FemCap* after childbirth, miscarriage, or abortion.

Possible Adverse Effects

- I. Although the *FemCap* has not been implicated, an association has been reported between diaphragm use and Toxic Shock Syndrome (T.S.S.), a rare but serious condition which can be fatal.
- II. As with any form of birth control, unwanted pregnancy may result. For a yearly effectiveness rate comparison, please ask your doctor or nurse.

Clinical trials in U.S. women showed that pregnancy rate of the first-time users of the second-generation *FemCap* ranged from 7.6 to 11.2 per 100 women for one year of use.

Symbols Glossary

	Prescription device Indicates that the product is a medical device as defined in 21 CFR 820.3(1) and Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Non-sterile Indicates a medical device that has not been subjected to a sterilization process
	Consult instructions for use Indicates the need to consult the instructions for use (IFU).
	Manufacturer Indicates the medical device manufacturer, as defined by EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC and MDR 2017/745.
	Recycled Packaging FSC Recycled labels identify products which are made with 100% recycled fiber. The mobius loop represents the total pre and post- consumer recycled fiber.

For updated information visit: www.femcap.com

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