The FemCap™
PHYSICIAN LABELING

The FemCap™ is a single-patient use, reusable vaginal barrier contraceptive device. It is available in three sizes based on the internal diameter: 22mm, 26mm and 30mm. It is composed entirely of medical grade silicone rubber. The device is washable, and reusable. FemCap™ must be used with Nonoxynol-9, a spermicide lubricant.

FemCap™ has a sailor’s-hat-shaped design. The small 22 mm FemCap™ weighs 9 grams, the medium 26 mm weighs 11 grams, and the large 30 mm weighs 14 (± 1) grams. The primary mechanism of action, when used with spermicide, is to prevent sperm from entering the cervix.

The FemCap™ is held in place by two forces: (1) the pressure/counter-pressure of the brim of the device as it flares outward against the walls of the vagina; and, to a lesser degree, (2) gripping the cervix by the lip within the rim. There is a strap over the dome of the device to aid in removal of the FemCap™.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR FAMILY PLANNING HEALTH CARE PROVIDER.

INDICATION FOR USE

FemCap™ is indicated for use by women of childbearing age who desire a barrier device to prevent or postpone pregnancy.

CONTRAINDICATIONS

+ This device should not be used in the presence of vaginal, cervical, or pelvic infections.
+ This device should not be used in the presence of vaginal or cervical lesions.

WARNINGS

> In the pivotal clinical study of FemCap™, it was observed that the chance of pregnancy for women who had delivered vaginally and who used the large size FemCap™ was approximately twice that of nulligravid women who used the small device or women who had delivered abdominally and who used the medium FemCap™. It is unknown whether the woman’s obstetrical history, the size of the device or the combination of the two was responsible for this observation. Nevertheless, women who have delivered vaginally and who are fitted with the large FemCap™ should be strongly cautioned before relying on the FemCap™ for contraception.

> Obstetrical history alone can predict the correct size of FemCap™ in approximately 85% of cases (eg. nulligravids with small size, gravidas without vaginal delivery with medium, and parous women who have delivered vaginally with the large FemCap™). However, obstetrical history is not predictive of the correct size FemCap™ in about 15% of women and there are insufficient data to predict how effective FemCap™ will be for these women.

> It is strongly advised that women be instructed to insert the FemCap™ prior to sexual arousal whenever possible to optimize the chance of correct placement. This is because lengthening of the vagina following arousal might make it more difficult for some women to correctly position the FemCap™ over the cervix.

> The FemCap™ is a single-patient use device. It may be reused only by the person for whom it is prescribed following cleaning and reapplication of spermicide.

> The FemCap™ should not be prescribed for any woman who can not insert and remove the device.

> The FemCap™ should not be prescribed for any woman in whom the device is not retained in a stable position covering the cervix. If the patient reports that FemCap™ dislodged during intercourse, the physician may wish to prescribe Emergency Contraception.

> Women should be counseled to contact a health care professional immediately if they notice a foul odor while the device is in place, or if the FemCap™ has a bad odor upon removal.

> Women with a history of sensitivity to spermicide or silicone should consider another form of contraception.

> FemCap™ should not be used during menstruation because it will prevent normal drainage of blood from the uterus and increase the risk of infection (such as Toxic Shock Syndrome) and pelvic pain.

PRECAUTIONS

+ FemCap™ will not help to reduce the risk of transmission of sexually transmitted infections (STIs). Women at increased risk for STIs, including HIV/AIDS, should use condoms.
+ FemCap™ must be inserted with a spermicide containing Nonoxynol-9.
+ FemCap™ should be left in the vagina for at least 6 hours following sexual intercourse. Removing it within 6 hours may lower its contraceptive efficacy.
+ FemCap™ should not be left in the vagina for more than 48 hours without removing and washing it.
+ Additional spermicide does not need to be applied if the woman has intercourse more than once within the 42 hours after inserting the device.
+ Studies have shown that Nonoxynol-9 is an epithelial irritant that may increase risk of disruption of vaginal epithelium, especially in women who use it frequently. (Refer to labeling for Nonoxynol-9 for additional Warnings and Precautions.)
+ The safety and effectiveness of FemCap™ during the 10-week post-partum period or the 6-week post-abortal period have not been established.
+ FemCap™ should be replaced if it shows signs of being worn or damaged such as holes, tears or other deterioration, e.g. discoloration of the FemCap™. Such changes in the material could cause injury to the woman or her partner, or increase the risk of pregnancy.
+ Women should be counseled to consult a health care professional if the following situations occur:
  - If she is not able to properly insert the FemCap™, because improper insertion and placement of the device may decrease its effectiveness as a contraceptive.
I! FemCup"

- If she or her partner experiences any pain during or following use of the FemCup™.
- If her partner notices abrasions on his penis, following intercourse using the FemCup™. If this occurs, she should consider another form of contraception.
- If she or her partner experiences any burning sensation within the urethra, develops urinary frequency, perineal pain, penile discharge and/or painful ejaculation. (These could be symptoms or signs of ascending infection, e.g. prostatitis.) He should report these symptoms to his physician. She should consider another form of contraception.
- If blood is noticed on the device when she removes it. (Blood on the device could be symptoms or signs of ascending infection, e.g. prostatitis.) He should report these symptoms to his physician. She should consider another form of contraception.
- If her partner reports a burning sensation within the urethra, develops urinary frequency, perineal pain. penile discharge and/or painful ejaculation. (These could be symptoms or signs of ascending infection, e.g. prostatitis.) He should report these symptoms to his physician. She should consider another form of contraception.

If a woman experiences a high fever and one or more of the other TSS symptoms, she should remove the FemCup™ and contact her health care provider immediately.

- Use caution when prescribing the FemCup™ for patients with a prior history of TSS.
- Use of this device may increase the risk of TSS. Counsel women to report possible signs and symptoms of TSS immediately.

Adverse Events

The Pivotal safety and efficacy study of FemCup™ utilized the First Generation device without the removal strap. Some of the most commonly reported adverse events in this study are presented below:

Table 1. Pivotal Clinical Study of First Generation FemCup™ without Removal Strap

<table>
<thead>
<tr>
<th>Body System/Symptom</th>
<th>FemCup with spermicide N</th>
<th>%</th>
<th>Diaphragm with spermicide N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Vaginosis</td>
<td>16</td>
<td>5.2</td>
<td>28</td>
<td>7.1</td>
</tr>
<tr>
<td>Blood In Vaginal Device</td>
<td>31</td>
<td>9.0</td>
<td>16</td>
<td>4.0</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>20</td>
<td>5.8</td>
<td>49</td>
<td>12.4</td>
</tr>
<tr>
<td>Genital Infection</td>
<td>15</td>
<td>4.3</td>
<td>23</td>
<td>5.8</td>
</tr>
<tr>
<td>Leukorrhea</td>
<td>16</td>
<td>4.6</td>
<td>29</td>
<td>7.3</td>
</tr>
<tr>
<td>Menstrual Disorder</td>
<td>16</td>
<td>4.6</td>
<td>23</td>
<td>5.8</td>
</tr>
<tr>
<td>UTI</td>
<td>26</td>
<td>7.1</td>
<td>49</td>
<td>12.4</td>
</tr>
<tr>
<td>Vaginal Cervix</td>
<td>26</td>
<td>7.1</td>
<td>49</td>
<td>12.4</td>
</tr>
<tr>
<td>Vaginitis (etiology unspecified)</td>
<td>34</td>
<td>9.8</td>
<td>48</td>
<td>12.1</td>
</tr>
</tbody>
</table>

(Done women in both arms of the study reported more than one type of problem.)

To improve ease of removal, the sponsor developed a Second Generation FemCup™ with a strap over the dome of the device. (In addition to the removal strap for all three sizes, the large size of the Second Generation FemCup™ added a slightly enlarged rim for improved stability.) A second, smaller (N=120) safety study was performed on this strapped device. Some of the most commonly reported adverse events from this study are presented below:

Table 2. Follow-up Study of Second Generation FemCup™ with Removal Strap

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>FemCup with spermicide N (%)</th>
<th>Diaphragm with spermicide N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal or pelvic pain or genital irritation (from device)</td>
<td>12/9 (9.3%)</td>
<td>14/13 (10.8%)</td>
</tr>
<tr>
<td>Blood in device</td>
<td>11/6 (18.3%)</td>
<td>23/21 (10.6%)</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>11/6 (18.3%)</td>
<td>12/10 (12.0%)</td>
</tr>
<tr>
<td>Leukorrhea</td>
<td>11/6 (18.3%)</td>
<td>12/10 (12.0%)</td>
</tr>
<tr>
<td>UTI</td>
<td>26/16 (50.0%)</td>
<td>49/49 (100.0%)</td>
</tr>
<tr>
<td>Vaginal Cervix</td>
<td>26/16 (50.0%)</td>
<td>49/49 (100.0%)</td>
</tr>
<tr>
<td>Vaginitis (etiology unspecified)</td>
<td>34/9 (9.8%)</td>
<td>48/12 (12.1%)</td>
</tr>
</tbody>
</table>

1 Some women in both arms of the study reported more than one type of problem.

Study Endpoints: The primary (efficacy) outcome measure was pregnancy. This was measured by urine pregnancy tests. All adverse experiences, grouped by body system, were the primary safety outcome measures. User acceptability was also evaluated by questionnaire and by interview regarding reasons for discontinuation from the study.

Method: The contraceptive efficacy study was a prospective, randomized, controlled clinical trial conducted at ten investigational sites. A total of 419 subjects were randomized to the FemCup™ and 422 were randomized to the diaphragm. Of these, 40 FemCup™ and 3 diaphragm subjects could not insert and/or remove the device and were excluded. Another 29 FemCup™ and 21 diaphragm subjects were also discontinued at baseline or lost to follow-up. Seven hundred and forty-eight subjects comprised the Per-protocol Population (350 FemCup™ and 398 diaphragm subjects). Approximately 40% of subjects in both groups had prior experience with the diaphragm. Of the 748 Per-protocol subjects, 226 were discontinued from the study (as discussed in the table below) and 30 were lost to follow-up.

Table 3. Patient Accountability

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>FemCup™ with Spermicide N (%)</th>
<th>Diaphragm with Spermicide N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Per-protocol Population&quot;</td>
<td>500</td>
<td>398</td>
</tr>
<tr>
<td>Not Vaginal Device</td>
<td>81</td>
<td>96</td>
</tr>
<tr>
<td>Vaginal Delivery</td>
<td>191</td>
<td>190</td>
</tr>
<tr>
<td>Discontinued</td>
<td>121</td>
<td>103</td>
</tr>
<tr>
<td>Per-protocol Violation</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>39</td>
<td>27</td>
</tr>
<tr>
<td>Device-related reason</td>
<td>21</td>
<td>8</td>
</tr>
<tr>
<td>Non-device-related reason</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Medical reasons</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Loss to follow-up</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Completed 6-month Study without becoming pregnant</td>
<td>214</td>
<td>294</td>
</tr>
</tbody>
</table>
Results

Primary Endpoint: Pregnancy Probabilities
The 6-month unadjusted gross cumulative pregnancy probabilities per 100 women in the Per-Protocol Population were 13.5% for FemCap™ users and 7.9% among the diaphragm users. The pregnancy probability was significantly higher for the FemCap™ users. The upper limit of the 95% confidence interval for the six-month cumulative pregnancy probability was 17.8%. The 12-month pregnancy probability of 22.8% with FemCap™ is a projected probability with an upper limit for the 95% confidence interval for 12 months of 30%.

Out of the 69 nulligravid subjects in this study who used the small FemCap™, 4 became pregnant for an 8.1% 6-month cumulative Kaplan Meier pregnancy probability. Of the 61 parous subjects who did not have a vaginal delivery and used the medium sized FemCap™, 4 became pregnant for an 8.2% 6-month cumulative Kaplan Meier pregnancy probability. In contrast, of the 184 subjects who had a vaginal delivery and used the large FemCap™, 28 became pregnant for a 17.3% 6-month cumulative Kaplan Meier pregnancy probability.

The following table shows pregnancy probabilities from different studies and various types of contraceptives compared to the FemCap™:

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Contraceptive Method</th>
<th>6-month Pregnancy Probability</th>
<th>12-month Pregnancy Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Sterilization</td>
<td>Less than 1%</td>
<td>Less than 1%</td>
<td></td>
</tr>
<tr>
<td>Injectable Hormones</td>
<td>2%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>IUDS</td>
<td>1-2%</td>
<td>1-2%</td>
<td></td>
</tr>
<tr>
<td>Hormone pills, vaginal ring</td>
<td>1-2%</td>
<td>1-2%</td>
<td></td>
</tr>
<tr>
<td>Male condom</td>
<td>7%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Cervical Cap</td>
<td>11%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Female condom</td>
<td>1%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>IUDs</td>
<td>11%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>IUDs</td>
<td>21%</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>Lea’s Shield</td>
<td>9%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>FemCap™ (All Sizes)</td>
<td>10%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>FemCap™ (All Sizes)</td>
<td>14%</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>FemCap™ (All Sizes)</td>
<td>29%</td>
<td>32%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Removal Problems</th>
<th>N=120 Strapped FemCap™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe problem</td>
<td>14 (12%)</td>
<td></td>
</tr>
<tr>
<td>Moderate problem</td>
<td>29 (24%)</td>
<td></td>
</tr>
<tr>
<td>Slight problem</td>
<td>21 (18%)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>56 (47%)</td>
<td></td>
</tr>
</tbody>
</table>

The proportions of women and men reporting awareness of the device, as opposed to pain/discomfort, were comparable with the two devices. However women in the strapped group were 2.8 times more likely than women in the unstrapped group to report pain/discomfort (p=0.0027); men in the strapped group were 2.1 times more likely than men in the unstrapped group to report pain/discomfort (p=0.0023). It is possible that the added emphasis in the strapped study on the partner’s experience may have caused a reporting bias for males.

PATIENT SELECTION

Best results can be expected from highly motivated and compliant women.

FITTING INSTRUCTIONS

The Instructions for Use should be followed (see below) during the initial fitting procedure. Normally, the FemCap™ is inserted by the patient and reviewed by the clinician, even during fitting. The patient should be given the device and the user instructions and should then be shown how to insert and remove the device. After removal, should be left alone to insert the device. If the insertion process is not successful, the clinician should provide further instructions until the patient is able to perform the procedure easily on her own. Patients who cannot demonstrate that they can insert, position, and remove their device in the clinic should be counseled to use another form of contraception.

The clinician should confirm that the device is in the correct position by pelvic exam, or by speculum, if needed. The plastic speculum should be inserted and the patient should be left alone to insert the device. The device should be fitted before the pelvic exam, or by plastic speculum, if needed. The plastic speculum should be inserted and the device inserted between women. The pelvic exam should be performed within 2-weeks of initial fitting to ensure correct fitting.

If a FemCap™ device is to be used for fitting a woman, be sure to clean the device (following the Instructions for Use, Care of the Device) and sterilize (autoclave, 121°C for 15 minutes) the fitting device. The fitting device is then inserted in the vagina.

PIVOTAL CLINICAL TRIAL

In the pivotal clinical trial, approximately 85% of women were assigned the correct size of FemCap™ based on obstetrical history as follows:

- Nulligravid women 22 mm
- Women who have not delivered vaginally 26 mm
- Women who have delivered vaginally 30 mm

It is possible that the size of the FemCap™ will need to be changed due to the size of the cervix. Problems with the device once the patient has left the clinic, such as discomfort during intercourse. In the pivotal study of the FemCap™, 85% of participants were correctly fitted based on obstetrical history alone. However, 10/418 (2.3%) could not be fitted at all, and 14/408 (3.4%) who could be fitted required a change in the size of the FemCap™. A follow-up visit should be scheduled within 2-weeks of initial fitting to ensure correct fitting.

If a FemCap™ device is to be used for fitting a woman, be sure to clean the device (following the Instructions for Use, Care of the Device) and sterilize (autoclave, 121°C for 15 minutes) the "fitting device" between women.

PATIENT COUNSELING

Women should be strongly advised to use the FemCap™, even during fitting. The patient should be given the device and the user instructions and should then be shown how to insert and remove the device. Afterwards, the patient should be left alone to insert the device. If the insertion process is not successful, the clinician should provide further instructions until the patient is able to perform the procedure easily on her own. Patients who cannot demonstrate that they can insert, position, and remove their device in the clinic should be counseled to use another form of contraception.

It is recommended that women have a back-up form of contraception available while they are learning how to use the FemCap™ in the event that the device is dislodged during intercourse. In the pivotal study of the FemCap™, 85% of participants were correctly fitted based on obstetrical history alone. However, 10/418 (2.3%) could not be fitted at all, and 14/408 (3.4%) who could be fitted required a change in the size of the FemCap™. A follow-up visit should be scheduled within 2-weeks of initial fitting to ensure correct fitting.

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Women should be advised that FemCap™ does not afford protection from sexually transmitted diseases.

Women should be strongly advised to insert the FemCap™ prior to sexual arousal whenever possible to optimize the chance of correct placement. This is because lengthening of the vagina following arousal might make it more difficult for some women to correctly position the FemCap™ without assistance from the clinician. If the patient has difficulty inserting or removing the device properly, the clinician should provide further instructions until the patient is able to perform the procedure easily on her own. Patients who cannot demonstrate that they can insert, position, and remove their device in the clinic should be counseled to use another form of contraception.

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PATIENT FOLLOW-UP

- A two-week follow-up visit after prescribing is recommended. The patient should wear the FemCap™ to the office. Confirm that the device is in the correct position by pelvic exam, or by plastic speculum if needed. The plastic speculum should be inserted HALF WAY into the vagina and opened at this point to avoid dislodging the FemCap™.

- After the initial two-week follow-up visit, the frequency of return visits should be determined on a case-by-case basis.

- If the patient becomes pregnant following FemCap™ fitting, the size of her cervix may change. Therefore, she must be refitted before she relies once again on the FemCap™ for contraception.

- During each follow-up visit, the vagina should be carefully inspected for evidence of pressure or allergic reaction. The patient should be questioned concerning any discomfort during coitus.

- Ask the patient to report any pain experienced by her or by her partner.

- Remind the patient to use the FemCap™ every time she has intercourse (except during menses).

- Instruct the patient to remove the FemCap™ no sooner than 6 hours after the last act of intercourse.

- Instruct the patient to remove and wash the FemCap™ with mild soap and water.

- Do not recommend wearing the FemCap™ more than 48 hours.

INSTRUCTIONS FOR USE

(These instructions are written for the patient.)

(In addition to these Instructions for Use, you should refer to the instructional video provided with your FemCap™.)

INSERTION

NOTE: Always wash your hands before handling and inserting the device.

Preparation:

Step 1: Find your cervix before inserting the FemCap™. To find your cervix, first bear down. This will bring your cervix closer to your finger. Next, insert a finger deep into your vagina. (The cervix feels like the tip of your nose, and its position can vary depending on the time of the month and your body position.) This will teach you how your cervix is positioned in your body. See Figure 1

Step 2: Next apply spermicide to the FemCap™. A total of about one teaspoon of commercially-available spermicide will be needed to coat your FemCap™. First, place 1/4 tsp in the bowl of your FemCap™, the part that will face your cervix. Don’t fill the bowl. See Figure 2.

Step 3: Place 1/2 tsp within the groove of the cap between the brim and the dome. The brim and dome will face into your vagina after you insert your FemCap™. See Figure 3.

Step 4: Apply spermicide in a thin layer over the outer brim except for the spots where your finger and thumb are holding the cap. See Figure 4.

Recommended Insertion Positions for FemCap™

Step 5: Choose a position for inserting your FemCap™ that works best for you. See Figures 5-a, 5-b and 5-c.

Position 1: Squatting

· Squat with both feet on the floor. See Figure 5-a.

Position 2: Leg-up Method

Stand with one leg raised on a chair or toilet seat. See Figure 5-b.

Position 3: Reclining with both knees bent

Recline on your back and bend both knees. See Figure 5-c.
Step 6: Hold your FemCap™ in one hand with the inside of the bowl facing up and the longer brim facing the body. Squeeze your thumb and finger together to flatten the FemCap™. See Figure 6.

Step 7: Separate the sides of your vaginal opening with your free hand and bear down to bring the cervix closer to your vaginal opening. Holding the FemCap™ in the squeezed, flattened position with the bowl facing up, insert your FemCap™ into your vagina with the long brim entering first. See Figure 7.

Step 8: Insert FemCap™ into your vagina, pushing it down toward the rectum and down and back as far as possible. See Figures 8-a and 8-b.

Step 9: Push your FemCap™ so that it covers your cervix completely. See Figure 9.

Step 10: Check to make sure that the FemCap™ is not partway between the vaginal opening and the cervix. The FemCap™ should be in the uppermost part of the vagina with the bowl covering the cervix. See Figure 10 for an example of incorrect FemCap™ position.

Step 11: Check the position of the FemCap™ immediately after you insert it. To check the position of the FemCap™, squat, bear down, insert your finger into your vagina, and feel for the FemCap™. See Figure 11.

Step 12: Press upwards on the strap and the dome for at least 10 seconds. See Figure 12.

Step 13: To remove the FemCap™, squat and bear down to bring the strap closer to your finger. See Figure 13.

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

REMOVAL

Do not remove FemCap™ sooner than six hours after the most recent sexual intercourse. This time interval is crucial because to remove it earlier may allow any remaining live sperm to enter the womb, thereby increasing the chances of pregnancy.

CAUTION: While removing the device, be careful to avoid scratching the vagina with a fingernail.

Step 10: Check to make sure that the FemCap™ is not partway between the vaginal opening and the cervix. The FemCap™ should be in the uppermost part of the vagina with the bowl covering the cervix. See Figure 10 for an example of incorrect FemCap™ position.

Figure 10
(Incorrect position)
**Step 14.** Rotate the *FemCap™* in any direction that is comfortable for you to hook it with your finger. See Figure 14.

![Figure 14](image)

Figure 14 illustrates possible rotations of the *FemCap™*. Choose the degree of rotation that is most comfortable for you.

**Step 15.** With muscles relaxed, push the tip of the finger against the dome of the *FemCap™* to dimple it. This will break the suction and allow room for the finger to fit between the dome and the removal strap. See Figure 15.

![Figure 15](image)

**Step 16:** After hooking the removal strap with the finger, gently pull the *FemCap™* out of your vagina. See Figure 16.

![Figure 16](image)

**Care of *FemCap™***

*FemCap™* is a medical grade silicone material that is compatible with water-based cleaning agents, lubricants, and with commercially available spermicidal gels.

To clean the *FemCap™*:

1. Wash the *FemCap™* thoroughly with antibacterial hand soap. Do not use heat, synthetic detergents, organic solvents, or sharp objects to clean the *FemCap™*.
2. Rinse it under tap water for one minute.
3. Examine the *FemCap™* for debris, and repeat the cleaning procedure if necessary.

4. Allow the *FemCap™* to air dry or gently pat it dry with a clean soft towel.
5. Store the *FemCap™* in the plastic storage container provided. See Figure 17.

![Figure 17](image)

The *FemCap™* should be replaced if it shows signs of wear or tear or deterioration.

**IMPORTANT INFORMATION**

- If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and other sexually transmitted diseases.
- Use of *FemCap™* will not reduce the risk of STIs.
- For contraceptive purposes, *FemCap™* works best when it is used consistently and correctly. It must be used with every act of intercourse (except during menses).

- Before trying *FemCap™* women should read the directions, watch the instructional video tape and be instructed by the health care provider in its proper use.

- Each woman should be counseled that if intercourse occurs within last 6 hours of the 48-hour maximum, she should remove the *FemCap™* during a “safe” interval (i.e., when more than 6 hours have elapsed since the last intercourse) and clean it. She should then reapply spermicide and reinsert the *FemCap™* prior to intercourse. Reinsertion resets the clock on the maximum wear time.

- While a couple is becoming accustomed to use of the *FemCap™*, they may wish to have a back-up form of contraception available such as a condom, in the event that they are not able to use the *FemCap™*. If necessary, they may wish to discuss Emergency Contraception with her doctor.

**0483** For further information, contact:

FemCap, Inc.
Del Mar, CA 92014

Phone: 1-877-4(FemCap)
Fax: 858-752-2624
Email: femcap@yahoo.com

www.femcap.com

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