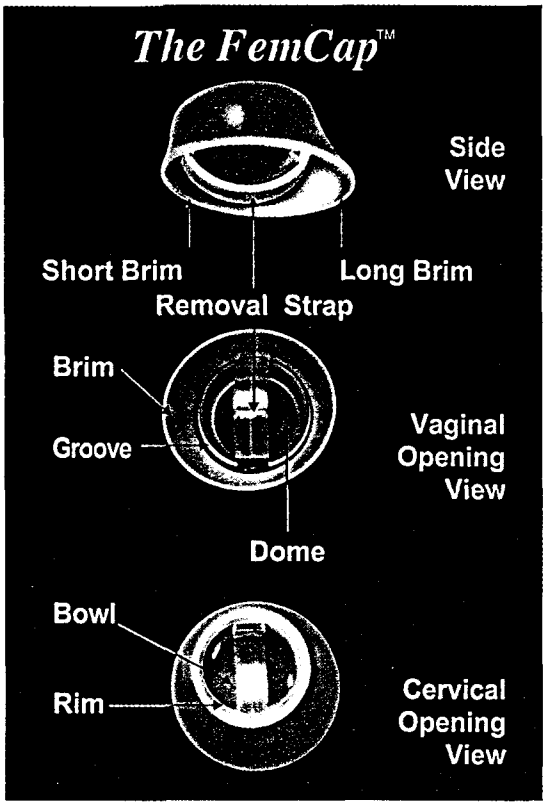
The FemCap™

PHYSICIAN LABELING



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 spermicidal 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. nulligravidas 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.

• If she or her partner is made uncomfortable by the presence of the *FemCap*™.

• If she or her partner experiences any pain during or following use of the *FemCap*™.

• If her partner notices abrasions on his penis, following intercourse using the *FemCap*™. If this occurs, 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 the *FemCap*™ slips out of place when she walks, coughs, sneezes, or strains.

• If blood is noticed on the device when she removes it. (Blood on the device may be the result of benign conditions such as midcycle spotting or menstruation. However, bloody discharge could be a sign of a medical condition or injury that may become serious if it is not treated.)

• If she is unable to remove the *FemCap*™.

♦ Toxic Shock Syndrome (TSS) has been linked to menstrual tampon and contraceptive diaphragm use. An association has not been established between the use of *FemCap*™ and TSS, however this remains a possibility. Symptoms of TSS include sudden high fever (usually 102° or more), vomiting, diarrhea, dizziness, fainting or near fainting when standing up, or a rash that looks like sunburn. Other signs of TSS may include sore throat, weakness, aching of muscles and joints, and redness of the eyes.

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

• Use caution when prescribing the *FemCap*™ 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 *FemCap*™ 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 *FemCap*™ without Removal Strap

Body System/Symptom	(N=346) FemCap with spermicide		(N=396) Diaphragm with spermicide	
	N	%	N	%
Bacterial Vaginosis	18	5.2	28	7.1
Blood in Vaginal Device	31	9.0	16	4.0
Dysmenorrhea	20	5.8	16	4.0
Genital Irritation	15	4.3	23	5.8
Leukorrhea	16	4.6	29	7.3
Menstrual Disorder	16	4.6	23	5.8
UTI	26	7.5	49	12.4
Vaginal Candidiasis	65	18.8	73	18.4
Vaginitis [etiology unspecified]	34	9.8	48	12.1

(Some 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 *FemCap*™ 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 *FemCap*™ added a slightly enlarged brim 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 *FemCap*™ with Removal Strap

	Strapped FemCap™ (N=97)			Unstrapped FemCap™ (N=358)[2] from Pivotal Study		
Adverse Event	Events	Women	%	Events	Women	%
Abdominal or pelvic pain or genital irritation [from device]	12	9	9.3	14	13	3.6
Blood in device	11	5	5.2	23	21	5.9
Dysmenorrhea	6	6	6.2	12	10	2.8
Leukorrhea	11	5	5.2	12	12	3.4
UTI	8	7	7.2	20	15	4.2
Vaginal Candidiasis	7	6	6.2	39	33	9.2
Vaginitis [etiology unspecified]	12	7	7.2	28	21	5.9

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

[1]Mauck C, Callahan M, Weiner DH, Dominik R, and the *FemCap*™ Investigators' Group, A comparative study of the Safety and Efficacy of *FemCap*™, a new vaginal barrier contraceptive, and the Ortho All-Flex Diaphragm. 1999, Contraception, Vol. 60, pp 71-80. (Note - The definiti of the Per Protocol Population used in this manuscript differs from that in the labeling).

2 The reason that the N=358 for First Generation *FemCap*™ in the above table differs from the N=346 in the preceding table, for what appears to be the same population, is that there were slight differences between the studie in the way rules for inclusion in analysis were implemented. The difference ir counts is due to differences in follow-up (observation time) between the two studies.

There was no evidence of greater cervical/vaginal irritation observed on gross examination among women who used the Second Generation *FemCap*™ compared with those who used the First Generation *FemCap*™ (7% vs. 6%, respectively).

The Second Generation *FemCap*™ with the removal strap is the only device that is being marketed.

SUMMARY OF PIVOTAL CLINICAL TRIAL OF UNSTRAPPED DEVICE FOR CONTRACEPTIVE EFFICACY[1]

Purpose: The purpose of this study was to evaluate the contraceptive efficac and safety of the first generation *FemCap*™ compared with the diaphragm. Both devices were evaluated when used with spermicidal lubricant.

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 regardin 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 *FemCap*™ and 422 were randomized to the diaphragm. Of these, 40 *FemCap*™ and 3 diaphragm subjects could not insert and/or remove the device and were excluded. Another 29 *FemCap*™ 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 FemCap™ 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. Reasons for discontinuation included pregnancy, device-related reasons, personal reasons unrelated to the device, medical reasons and protocol violations. Four hundred and ninety two participants, 214 in the *FemCap*™ group and 278 in the diaphragm group, completed the six-month study without becoming pregnant.

Table 3. Patient Accountability

Number of Patients	*FemCap*™ with Spermicide	Diaphragm with Spermicide
"Per-protocol Population"	350	398
Nulligravid	81	98
Non-Vaginal Delivery	78	110
Vaginal Delivery	191	190
Discontinued	123	103
Protocol Violation	24	21
Pregnancy	39	27
Device-related reason	21	8
Non-device related reason	20	25
Medical reasons	19	22
Loss to follow-up	13	17
Completed 6-month Study without becoming pregnant	214	278

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 4

Contraceptive Method	6-month Pregnancy Probability	12-month Pregnancy Probability
• Surgical Sterilization • Injectable Hormones • IUDs	Less than 1%	Less than 1%
Hormone pills, vaginal ring	1-2%	1-2%
Male condom	7%	11%[1]
Contraceptive Diaphragm	8%	17%
Cervical Cap	11%	17%
Female condom	13%	21%[1]
Lea's Shield	9%	15%[1]
FemCap™ (All Sizes)	(13.5%)	(23%)[1]
22mm, nulligravid	8.1%	14%[1]
26mm, parous (non-vaginal)	8.2%	14%[1]
30mm, parous (vaginal)	17.3%	29%[1]

[1]These 1-year probabilities are projected since most barrier studies today are conducted as 6-month studies.

Study Endpoint: Device Acceptability

Of the 419 ***FemCap***™ subjects enrolled in the study, 10.5% (44) were unable to insert and/or remove the device at enrollment or at the 2-week visit. Of the 350 per-protocol subjects, 10.3% (36) reported difficulty with insertion and 11.7% (41) reported difficulty with removal of the device. In addition, 30.6% (107/350) of the patients reported that the device rotated or was dislodged during use. Due to the high rates of problems with insertion and removal of the device, the ***FemCap***™ was modified to include a removal strap.

Forty-seven women were enrolled in a pilot study to evaluate the removal strap. These women had previously had difficulty inserting or removing the First Generation ***FemCap***™. Eighty-one percent of these subjects reported that the strap made removal of the ***FemCap***™ easier.

The study (N=120) of the strapped ***FemCap***™ (among women without prior ***FemCap***™ experience) also evaluated device acceptability. The results of this study are listed in the table below. The strap did not significantly improve removal over the First Generation unstrapped ***FemCap***™.

Table 5.

Removal Problems	N=120 Strapped ***FemCap***™
Severe problem	14 (12%)
Moderate problem	29 (24%)
Slight problem	21 (18%)
None	56 (47%)

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=.0027); men in the strapped group were 2.1 times more likely than men in the unstrapped group to report pain/discomfort (p=.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 fi ting procedure. Normally, the ***FemCap***™ is inserted by the patient and n by the clinician, even during fitting. The patient should be given the devic and the user instructions and should then be shown how to insert and remove the device. Afterwards, she should be left alone to insert the devic herself. After insertion, placement should be checked by bimanual exam a by speculum exam if indicated. The patient should then remove the devic without assistance from the clinician. If the patient has difficulty inserting o removing the device properly, the clinician should provide further instructio until the patient can perform these procedures 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 plastic speculum, if needed. The plastic speculum shou be inserted HALFWAY into the vagina and opened at this point to avoid di lodging the ***FemCap***™. The device may be considered correctly in place when the insertion instructions have been correctly followed, the device is comfortable for the woman and the cervix is covered.

In the pivotal clinical trial, approximately 85% of women were assigned the correct size of ***FemCap***™ on the basis of 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 problems with the device once the patient has left the clinic, such as dislodgement 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-u visit should be scheduled within 2-weeks of initial fitting to ensure correct fi during use.

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 **steri ize** (autoclave, 121°C for 15 minutes) the "fitting device" between women.

PATIENT COUNSELING

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** sexu al 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 th cervix.

Women should check the ***FemCap***™ both prior to and after intercourse t confirm correct position. Incorrect position and device dislodgement may result in pregnancy. If the ***FemCap***™ was dislodged during intercourse, the patient may wish to discuss Emergency Contraception with her physician.

It is recommended that women have a back-up form of contraception avail able while they are learning how to use the FemCap™ in the event that th are not able to use the ***FemCap***™ for contraception.

Women should be advised that the ***FemCap***™ is a single-patient use device and may not be shared with other users.

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 HALFWAY 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

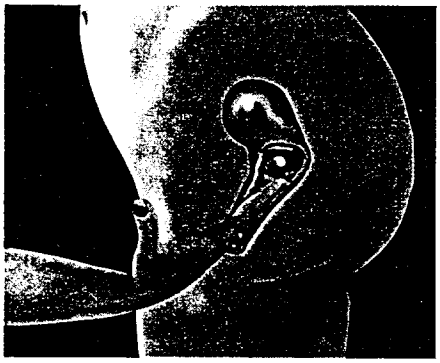


Figure 1

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.

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.

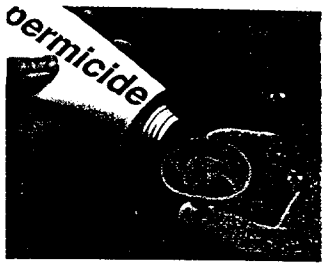


Figure 3

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.

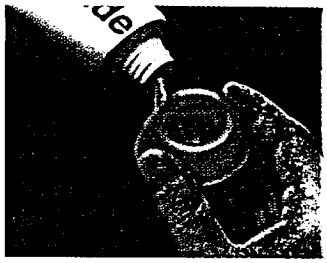


Figure 4

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.

Figure 5-a

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.

Figure 5-b

Position 3: Reclining with both knees bent

Recline on your back and bend both knees. See Figure 5-c.

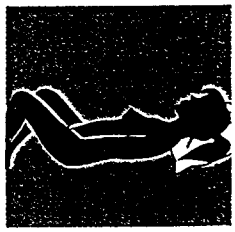


Figure 5-c

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.

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.

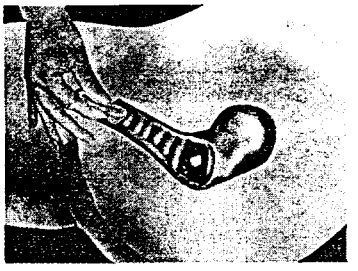


Figure 7

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.

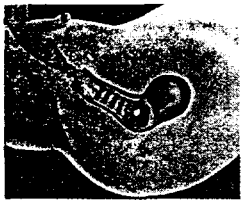


Figure 8-a

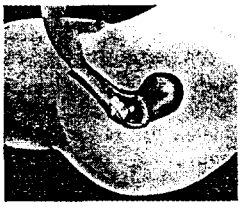


Figure 8-b

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

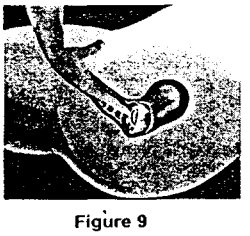


Figure 9

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.

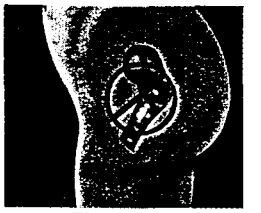


Figure 10
(Incorrect position)

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.

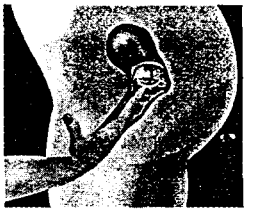


Figure 11

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

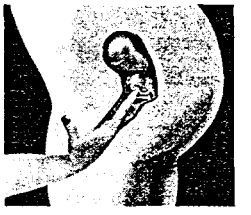


Figure 12

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

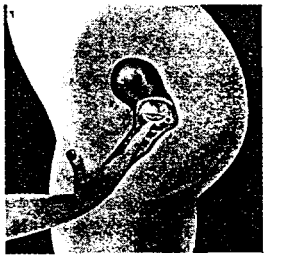


Figure 13

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

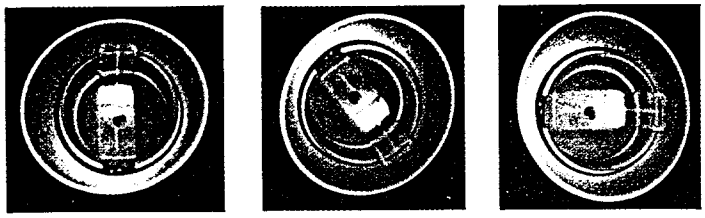


Figure 14

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.

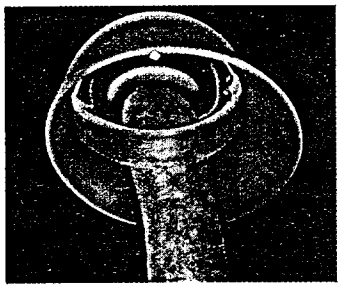


Figure 15

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

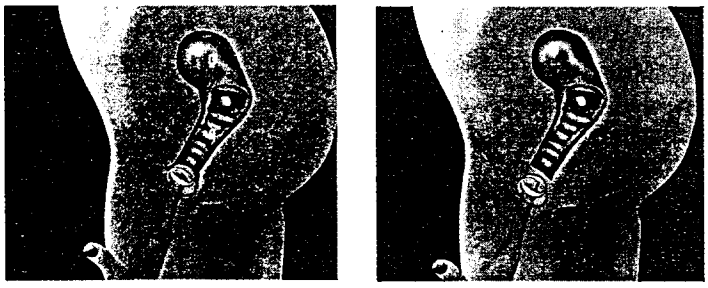


Figure 16

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 clea soft towel.
5. Store the *FemCap*™ in the plastic storage container provide See Figure 17.

Figure 17

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

IMPORTANT INFORMATION

• If used properly, latex condoms will help to reduce the risk transmission of HIV infection (AIDS) and other sexually transm ted diseases.

* Use of *FemCap*™ will **not** reduce the risk of STIs.

• For contraceptive purposes, *FemCap*™ works best when it used consistently and correctly. It must be used with eve act of intercourse (except during menses).

• Before trying *FemCap*™ women should read the direction watch the instructional video tape and be instructed by the heal care provider in its proper use.

• Each woman should be counseled that if intercourse occu within last 6 hours of the 48-hour maximum, she should remo the *FemCap*™ during a "safe" interval (i.e. when more than 6 hou have elapsed since the last intercourse) and clean it. She shou then reapply spermicide and reinsert the *FemCap*™prior to inte course. Reinsertion resets the clock on the maximum wear tim

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

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Date of Printing July 28, 2003