

SECTION 2.8 BARRIER METHODS

I. Diaphragm

- A. Non-contraceptive benefits
 - 1. Protection from some sexually transmitted infections.
 - 2. Lower risk of cervical dysplasia and cancer.
- B. Subjective data – History as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services)

Cautions - The following conditions may preclude satisfactory use or make use of the diaphragm inadvisable:

- 1. History of Toxic Shock Syndrome.
 - 2. Allergy to rubber, latex, polyurethane, or spermicide.
 - 3. Recurrent urinary tract infections.
 - 4. Abnormalities in vaginal anatomy that interfere with satisfactory fit or stable placement.
 - 5. Inability of client to correctly insert or remove.
 - 6. Full-term delivery less than 6 weeks ago.
 - 7. Need for HIV protection -**There is a lack of protection against HIV and some STIs. Client must use a condom if at risk.**
 - 8. **A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (diaphragm with spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4 ((Centers for Disease Control (CDC) U.S. Medical Eligibility Criteria for Contraceptive Use, (USMEC) 2010. MMWR Early Release 2010; 59 May 28, 2010).**
 - 9. **In client with HIV or AIDs, use of spermicides and/or diaphragms (with spermicide) can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3 (USMEC 2010).**
 - 10. **The contraceptive effectiveness of diaphragms and cervical caps without nonoxynol-9 has been insufficiently studied and should be assumed to be less than that of diaphragms and cervical caps with nonoxynol-9. (Zieman M., Hatcher RA, et al. A Pocket Guide to Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2010).**
- C. Objective data
 - 1. Physical examination as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services).
 - 2. Laboratory tests as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services).
 - D. Assessment and plan - Client education/informed consent
 - 1. The client will sign an informed consent prior to being fitted with the diaphragm.

SECTION 2.8 BARRIER METHODS

2. The client shall be taught the use and care of the diaphragm.
 3. Document that the client demonstrates the ability to properly insert and remove the diaphragm.
 4. Document that literature and instructions, including the package insert, for diaphragm use were given.
 5. The client should be able to leave the diaphragm in place for a minimum of 6-8 hours without discomfort at least once before she uses it for contraception.
 6. Client should be informed that if she wishes to become pregnant, she simply needs to discontinue the use of the diaphragm.
 7. The client should also leave the diaphragm in place for a minimum of 6-8 hours at least once before returning for a fit check.
 8. Counsel regarding emergency contraception in the event the diaphragm is not used, or becomes dislodged during use.
- E. Side effects and complications
1. Toxic Shock Syndrome
Sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles and joints, and rash (like a sunburn) occurring in association with use of diaphragm has been reported.
 2. Recurrent cystitis
 - a. Spermicide use can encourage selective colonization of the vagina with anaerobic bacteria and uropathogens (Hooten, 1996).
 - b. Researchers have documented that spermicide exposure is an important risk factor for UTIs, although it is possible that mechanical factors associated with diaphragm use may also contribute to the development of UTIs in some women (Fihn, 1996).
 - c. Consider changing spermicides or the birth control method depending on the severity of symptoms.
 3. Vaginal infections- use of a diaphragm with spermicide can increase vaginal colonization with candida (Elias, 1993).
 4. Allergic reaction to rubber, latex, polyurethane, or spermicide and/or local skin irritation of client or partner.
 5. Pelvic discomfort, cramps, or pressure on the bladder or rectum due to improper fit.
 6. Rare cases of vaginal trauma, including abrasion or laceration.
 7. Foul odor or vaginal discharge if the diaphragm is left in the vagina for longer than recommended.
- F. Follow up visits
1. A revisit must be offered approximately one month after the initial fitting.
 - a. During the first month of use, the client is instructed to practice insertion and removal, and to determine the comfort of the diaphragm.

SECTION 2.8 BARRIER METHODS

- b. The day of the appointment, the client is to wear the diaphragm to the clinic. The clinician should check the position and fit of the diaphragm.
2. The client should return annually for exams and evaluation of the diaphragm fit.
3. The diaphragm should be refit annually after a weight gain or loss of 10 pounds or more, after an abortion, or after a full-term pregnancy. Remind the client to avoid wearing the diaphragm for the last 2-3 days before routine exams to provide optimal conditions for the Pap test.
4. The client should be encouraged to call the clinic if she experiences problems with the diaphragm.

II. Foams, Jellies, Creams, Suppositories, Vaginal Contraceptive Film

A. Non-contraceptive benefits

Available without a prescription.

B. Subjective data

Cautions - spermicides are not a reasonable choice in the following circumstances:

1. Spermicidal condoms for anal sex.
2. Vaginal intercourse multiple times each day.
3. **A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4 (USMEC 2010).**
4. **In client with HIV or AIDs, use of spermicides can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3 (USMEC 2010).**
5. Allergy or sensitivity to spermicide.
6. Abnormalities in the vaginal anatomy preventing proper insertion or retention of spermicide.
7. Inability to learn correct insertion technique.

C. Assessment and plan – Client Education

1. Clients should be advised to incorporate the use of the condom to increase the effectiveness of spermicidal creams, jellies, foams, suppositories, and film.
2. Clients are to be provided with appropriate fact sheets specific to their product of choice and should be instructed to follow the package insert for directions on use.
3. Counsel regarding emergency contraception in the event the spermicide is not used according to directions.

D. Side effects and complications

SECTION 2.8 BARRIER METHODS

1. Temporary skin irritation or allergy (male or female).
2. Selective colonization of the vagina with anaerobic bacteria and uropathogens, which can result in bacterial vaginosis or UTI (Hooten, 1996).
3. Unpleasant taste during oral-genital sex.
4. Failure of suppositories to melt or foam in the vagina, which may decrease effectiveness.
5. There is no confirmed association between the use of spermicide and birth defects (Simpson, 1990).

III. FemCap®

A. Non-contraceptive benefit

Possible protection against sexually transmitted infections affecting the upper genital tract.

B. Subjective data - History as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services)

Cautions - The following conditions may preclude satisfactory use or make use of FemCap inadvisable:

1. History of Toxic Shock Syndrome.
2. **CIN or cervical cancer**
3. Allergy to spermicide, rubber, latex or polyurethane.
4. Abnormalities in vaginal anatomy that interfere with a satisfactory fit or stable placement.
5. Vaginal bleeding from any cause, including menstrual flow.
6. Full-term delivery within the past 6 weeks or recent spontaneous or induced abortion.
7. Inability of client to correctly insert or remove.
8. Need for HIV protection.
9. **High risk for HIV – Repeated and high-dose use of the spermicide nonoxynol-9 has been associated with creased risk for genital lesions, which might increase the risk of HIV infection. Catagory 4 (USMEC 2010)**
10. **HIV infection - Use of spermicides can disrupt the cervical mucosa, which may increase viral shedding and HIV transmission to uninfected sex partners. Category 3 (USMEC 2010)**
11. **Women at high risk for HIV should avoid using cervical caps to which nonoxynol-9 has been added. The contraceptive effectiveness of diaphragms and cervical caps without nonoxynol-9 has been insufficiently studied and should be assumed to to be less than that of diaphragms and cervical caps with nonoxynol-9 (Zieman M., Hatcher RA, et al. A Pocket Gude to Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2010)**

C. Objective data

SECTION 2.8 BARRIER METHODS

1. Physical examination as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services)
 2. Laboratory tests as per Title X Guidelines (See Nursing Policy Section 1.4 – Health Care Services)
- D. Assessment and plan – Client Education
1. The client will sign an informed consent for the FemCap.
 2. The client shall review the use and care of the FemCap.
 3. Document that instructions for FemCap use were reviewed.
 4. Document that the client demonstrates the ability to properly insert and remove the FemCap.
 5. Instruct the client to stop using the FemCap and return to clinic for evaluation if symptoms of vaginal or cervical irritation develop.
 6. Client should be informed that if she wishes to become pregnant, she simply needs to discontinue the use of the FemCap.
 7. Advise the client of signs and symptoms of Toxic Shock Syndrome (TSS) and instruct her to seek emergency medical care if they occur.
 8. Counsel regarding emergency contraception in the event the FemCap becomes dislodged or is not used properly.
- E. Side effects and complications
1. Toxic Shock Syndrome - sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles, and joints and rash (like a sunburn) has occurred in association with use of the cervical cap.
 2. Allergic reaction to rubber, latex, polyurethane or spermicide, or local skin irritation to either client or partner.
 3. Rare cases of vaginal/cervical trauma, including abrasion or laceration.
 4. Foul odor or vaginal discharge if the FemCap is left in the vagina longer than recommended (48 hours maximum).
- F. Follow up visits
1. The client should return annually for exams and recheck of the FemCap fit. Remind the client to avoid wearing the FemCap for 2-3 days before a routine exam to provide optimal conditions for the Pap **test**.
 2. The client should return for an examination and to have the cervical cap fit checked six weeks after childbirth, miscarriage, abortion, or pelvic surgery, including LEEP or conization.

IV. Condom (male and female)

- A. Non-contraceptive benefits
1. Protection against sexually transmitted infections, including HIV.
 2. Available without a prescription at low cost.

SECTION 2.8 BARRIER METHODS

3. Male participation in contraception.
4. Prevention of premature ejaculation.
5. Prevention of sperm allergy in women.

B. Subjective data

Cautions - Male condoms do have disadvantages that may lead to inconsistent or lack of use. Encourage couples to try different brands and lubricants until they find one that is acceptable.

1. Allergy to latex or spermicide in condoms. Plastic condoms are an excellent alternative.
2. An inability, in some men, to maintain an erection if condom is used.
3. Male partner will not accept responsibility for birth control.
4. Natural membrane condoms are contraindicated where there is a risk of infection since they allow passage of very small viruses such as the human immunodeficiency virus (HIV).
5. Condoms with spermicidal lubricant should not be used for anal intercourse; for multiple acts of vaginal intercourse each day (>2 times); or for those at high risk for HIV.

C. Assessment and plan – Client Education

1. The client must be given a condom fact sheet. Advise that female condoms may be squeaky during use.
2. For additional contraceptive benefit, advise the use of spermicide with condoms, with the exception of anal intercourse, multiple acts of vaginal intercourse each day (>2 times), and high risk for HIV.
3. Counsel regarding emergency contraception in the event of condom breakage.

D. Side effects and complications

1. Breakage.
2. Allergy or skin irritations.

SECTION 2.8 BARRIER METHODS

The following is a sample Condom Information Sheet. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

HOW TO USE CONDOMS

Use latex or plastic condoms to protect against sexually transmitted infection, including the HIV. When used correctly, condoms also provide some protection against pregnancy. Using a sperm killing cream, jelly or film (called spermicide) with the condom gives more protection from pregnancy. However, studies suggest that the use of condoms with spermicide should not be recommended in the following situations: anal sex; multiple acts of intercourse every day; by persons at risk of HIV. Please ask your health care provider if you have any questions about the use of condoms with spermicidal lubricant.

Before sex

- Always keep some latex or plastic condoms and water-based lubricant around. Have extra condoms available in case one gets ripped before use, gets put on wrong, or in case you want to have sex more than once.
- It's a good idea to talk about condom use with your partner *before* you have intercourse.

When you have sex

- Open the condom package carefully. Be careful not to tear or make holes in the condom with fingernails, teeth, or other sharp objects.
- Put on the condom, once the penis is erect, before the penis comes in contact with the partner's mouth, anus, or vagina. If the penis is uncircumcised, pull the foreskin back before putting on the condom. Keep the condom on the penis until after the man ejaculates (comes).
- Unroll the condom a little so you can see which way the condom unrolls. (The rolled ring should be on the outside.) Hold the tip of the condom and unroll it down to the base of the erect penis. If the condom does not unroll easily, it is on upside-down. Throw it away and begin with a new condom. (Sperm and infectious organisms from the fluid on the penis could already be on one side of the condom, so don't just turn it over, throw it out.
- Use enough lubrication. For latex condoms, use only water-based lubricants like water; lubricating jellies (like K-Y Jelly); or spermicidal creams, jellies, foam, or suppositories. **DO NOT** use oil-based lubricants like cold cream, mineral oil, cooking oil, petroleum jelly, body lotions, massage oil, or baby oil. They can damage latex condoms. (For plastic condoms, like the brand Avanti® or female condoms like Reality®, any type of lubricant can be used).
- If the condom breaks or falls off during sex but before the man ejaculates (comes), stop and put on a new condom. Change to a new condom if the penis is moved from one area of the body to another (for example from the vagina to the anus).

SECTION 2.8 BARRIER METHODS

After Sex

- Soon after ejaculation, take the penis out of the vagina, while it is still erect. Hold the condom firmly against the base of the penis so it will not slip off and so that no semen leaks out of it.
- Check the condom for visible damage such as holes, and then wrap it in tissue and put it in the trash. Do not flush condoms down the toilet.
- If the condom breaks, falls off, leaks, or is not used:
- Discuss the possibility of pregnancy or infection with your partner and contact your health care provider as soon as you can. Do not douche. Emergency contraception may be used to prevent pregnancy if started within 72 hours of having unprotected intercourse. Call 1-888-NOT-2-LATE to learn more about emergency contraceptives. This is a free phone call.
- Insert an applicator full of spermicide into the vagina as soon as possible. Gently wash the penis, vulva, anus, and the general area with soap and water immediately after intercourse to help reduce the risk of getting a sexually transmitted infection.

If you have sex more than one time

Use a new condom from "start to finish" with each act of anal, vaginal, or oral intercourse. Do not use the same condom more than one time.

Taking care of supplies

- Store condoms in a cool and dry place out of direct sunlight (heat may weaken latex). Latex condoms can probably be stored in a wallet for up to 1 month when kept away from heat and sunlight.
- Check the expiration or manufacture date on the box or individual package of condoms. Expiration dates are marked as "Exp"; otherwise, the date is the manufacture date (MFG). Latex condoms should not be used beyond their expiration date or more than 5 years after the manufacturing date. Latex condoms with spermicide should probably be used within 2 years of the manufacture date. Condoms in damaged packages or that look brittle, sticky or discolored should not be used, regardless of their expiration date.

SECTION 2.8 BARRIER METHODS

The following is a sample Diaphragm Information Sheet. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

HOW TO USE YOUR DIAPHRAGM

The diaphragm fits inside the vagina and covers the cervix, (the opening to the uterus). The diaphragm stops sperm from getting into the uterus. The diaphragm only works as a method of birth control if used with sperm-killing cream or jelly (spermicide). The spermicide used with the diaphragm kills any sperm that swim over the rim of the diaphragm. To prevent pregnancy, the diaphragm must be used every time you have sex.

- The diaphragm may be inserted just before you have sex, or up to 6 hours before having sex.
- Fill the middle of the diaphragm with one teaspoon of sperm killing cream or jelly (called spermicide). Spread the cream around the inside of the diaphragm with your finger.
- To insert the diaphragm, you must be in a comfortable position. You may squat, lie down, or stand with one foot resting on the edge of a chair, a bathtub or a toilet seat lid.
- Squeeze the sides of the diaphragm together. Insert it, with the side containing the spermicide up, into your vagina, pushing in and back as far as it will go.
- Check to be sure that the diaphragm is in place. You should be able to feel your cervix through the diaphragm when you insert your finger into your vagina. Your cervix will feel firm, like the tip of your nose. You should be able to feel the rim of the diaphragm just behind your pubic bone.
- Leave the diaphragm in for at least six to eight hours after having sex. (This is to allow time for all the sperm to be killed before you remove it.) If you have sex more than once leave the diaphragm in and put one applicator full of sperm killing cream or jelly into your vagina. Remember to leave the diaphragm in place for at least six to eight hours after the last time you had sex. Do not leave the diaphragm in place for longer than 24 hours if possible.
- To take out the diaphragm, hook a finger over or under the rim. Pull down and out.
- After use, wash your diaphragm with mild soap and water. Rinse and pat dry. Store the diaphragm in its carrying case.
- Check your diaphragm for tears or holes before you use it. To do this, hold the diaphragm up to the light, or fill with water and examine closely.
- Never use products like Vaseline®, cold cream, hand lotion, vegetable oil, yeast medication, vaginal hormone creams or baby powder on your diaphragm. They can damage the rubber.

**SECTION 2.8
BARRIER METHODS**

The following is a sample Diaphragm Consent Form. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

DIAPHRAGM CONSENT

Client Name _____

I understand that the diaphragm is a dome-shaped rubber cup that works by covering the opening of the cervix and holding a sperm killing cream or jelly (spermicide) in place. I understand that about 20% of women using the diaphragm will become pregnant during the first year of use. I can increase the effectiveness of the diaphragm by having my partner use condoms. The advantages of the diaphragm include: It can be left in for 24 hours after sex; there are fewer side effects than with other birth control methods. I also understand that if I want to discontinue this method, I just stop using it. If I do not wish to become pregnant, I must start using another method immediately.

I know that I need to do the following for the diaphragm to work:

- Use it every time I have sex.
- Use spermicide with the diaphragm and add more cream or jelly to the vagina for each additional act of sex.
- Leave the diaphragm inside my vagina for at least 6 hours after the last time I have sex but for no longer than 24 hours.
- Check the diaphragm before I use it to make sure it has no holes, cracks, weak spots or tears.

I understand that I should come back to the clinic and have the size of my diaphragm checked after:

- Pregnancy
- Abortion or a miscarriage
- Pelvic surgery
- Lose or gain 10 or more pounds

I understand that problems or side effects of the diaphragm include:

- Problems putting it in or taking it out.
- Allergy to the rubber or the spermicide.
- Vaginal or urinary tract infections.

I understand that I should call the clinic immediately if I notice:

- Unusual vaginal discharge, itching, irritation or frequent vaginal infections.
- Painful urination or frequent bladder/urinary tract infections.
- Pain or cramping when the diaphragm is in place or problems using the diaphragm.
- Signs or symptoms of Toxic Shock Syndrome, which include: sudden high fever, vomiting/diarrhea, dizziness, sore throat, aching muscles, and rash (like a sunburn).

I understand that the diaphragm and spermicide use is not recommended for women at high risk for HIV infection or who are HIV positive:

- The use of the spermicide nonoxynol-9 may increase the risk for contracting HIV.
- The use of spermicides and/or diaphragm (with spermicide) may increase viral shedding and HIV transmission to uninfected partners.

This acknowledges that I have been given the opportunity to review the information on this and other methods of birth control. I understand the risks and benefits of each method. I have had the opportunity to ask questions, and have had them answered to my satisfaction.

Client's Signature _____ Date _____ Staff Signature _____ Date _____

INTERPRETER'S STATEMENT

I have translated the information and advice presented orally to the client who has chosen a diaphragm. I have also read this consent to her in a language she understands and explained its content to her. To the best of my knowledge and belief she understands this explanation and voluntarily consents to the use of the diaphragm.

Interpreter's Signature _____ Date _____

**SECTION 2.8
BARRIER METHODS**

The following is a sample FemCap Consent Form. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

FEMCAP CONSENT

Client Name

I understand that the FemCap works by covering the opening of the cervix and holding a sperm-killing cream or jelly (spermicide) in place. I understand that about 20-40% of women using the FemCap will become pregnant during the first year of use. I can increase the effectiveness of the cap by having my partner use condoms. The advantages of the FemCap include: It can be left in place for 48 hrs after sex. If I wish to discontinue use of this method, I just stop using it. If I do not wish to become pregnant, I must start using another method immediately.

I know that I need to do the following for the FemCap to work:

- Use it every time I have sex.
- Check to see that the cap is in place on the cervix before I have sex.
- Use spermicide with the cap.
- Leave the cap inside my vagina for at least 6 hours after the last time I have sex but for no longer than 48 hours.
- Check the cap before I use it before I use it to make sure it has no holes, cracks, weak spots or tears.

I understand that I should come back to the clinic and have the size of my FemCap checked after a pregnancy, an abortion or a miscarriage, or pelvic surgery. I understand that I should not use the FemCap during my period, when I have vaginal bleeding for any reason, or if I have unusual vaginal discharge or irritation.

I understand that problems or side effects of the FemCap include:

- Problems putting it in or taking it out.
- Allergy to the rubber or spermicide.
- Cap may come off during sex and I could get pregnant.
- Vaginal discharge, odor, or vaginal infections.

I understand that I should call the clinic immediately if I notice:

- Unusual vaginal discharge, itching, irritation, or frequent vaginal infections.
- Problems using the cap (falling off the cervix, pain, discomfort).
- Signs or symptoms of Toxic Shock Syndrome which include sudden high fever, vomiting, diarrhea, dizziness, sore throat and aching muscles or rash (like a sunburn).

I understand that the Femcap and spermicide use is not recommended for women at high risk for HIV infection or who are HIV positive:

- The use of the spermicide nonoxynol-9 may increase the risk for contracting HIV.
- The use of spermicides or the Femcap (with spermicide) may increase viral shedding and HIV transmission to uninfected partners.

This acknowledges that I have been given the opportunity to review the information on this and other methods of birth control. I understand the risks and benefits of each method. I have had the opportunity to ask questions, and have had them answered to my satisfaction.

Client's Signature

Date

Staff Signature

Date

INTERPRETER'S STATEMENT

I have translated the information and advice presented orally to the client who has chosen a FemCap. I have also read this consent to her in a language she understands and explained its content to her. To the best of my knowledge and belief she understands this explanation and voluntarily consents to the use of the FemCap.

Interpreter's Signature

Date

**SECTION 2.8
BARRIER METHODS**

The following is a sample FemCap Evaluation Form. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

FEMCAP EVALUATION		
Client Name _____	Date _____	
Birthdate _____		
When was the first day of your last period? _____	Was this a normal period?	? Yes ? No
How long have you been using the Femcap? _____		
Check if you have had any of the following since you started using the Femcap:		
? Vaginal burning, discharge, irritation or itching?		
? Painful or frequent urination or bladder/urinary tract infections?		
? Signs or symptoms of Toxic Shock Syndrome which include sudden high fever, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles and joints and rash (like sunburn)?		
? Pain or cramping when the Femcap is in place?		
? Any other problems with your Femcap? _____		
Please answer the following:		
How long should the Femcap be left in place after intercourse?		
? For at least 6 hours	? For 2 hours	? For 48 hours
When should the fit of the Femcap be rechecked?		
? After you have a baby		
? If the Femcap will not stay on the cervix		
? Both of the above		
Do you have any questions about the Femcap? ? Yes ? No		

Client's Signature _____	Date _____	Staff Signature _____
Date _____		
TO BE COMPLETED BY CLINIC STAFF		
S:		
O:		
A:		
P:		
Return to clinic: _____		

Staff Signature _____	Date _____	