

## DIAPHRAGM

### I. INTRODUCTION

The contraceptive diaphragm is a dome-shaped latex or silicone device that serves as a mechanical barrier against the cervix and holds a spermicidal preparation in place within the vagina. The diaphragm is one of the oldest contraceptive methods, is non-hormonal, and easy to use.

Efficacy with perfect use results in 6 pregnancies in 100 users per year-- versus 16 pregnancies per 100 users per year with typical use.

### II. CLIENT SELECTION

- A. Indications – The diaphragm may be an appropriate method of contraception for women who:
  - 1. Prefer an intercourse-related non-hormonal method of contraception
  - 2. Desire a barrier method that can provide continuous protection for up to 24 hours.
- B. Contraindications – (USMEC 3-- Risks outweigh advantages for method use; USMEC 4--Unacceptable risk for method use):
  - 1. History of toxic shock syndrome (TSS) (USMEC 3).
  - 2. Allergy to product components (USMEC 3).
  - 3. High Risk for HIV/AIDS (USMEC 4).
  - 4. HIV/AIDS (USMEC 3).
  - 5. Antiretroviral (ARV) (USMEC 3).

### III. MANAGEMENT OF WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

Consultation with site Medical Director should occur before providing a diaphragm to clients in any of the following situations:

- A. Less than 3 months since cervical surgery (including colposcopy with biopsy cryotherapy, LEEP, laser therapy, or knife cone biopsy).
- B. Less than 2 weeks since mid-trimester abortion or less than 6 weeks post-partum.
- C. Recent history of frequent lower urinary tract infections, especially if associated with prior diaphragm use.

### IV. MEDICAL SCREENING, FITTING AND EVALUATION

- A. Comprehensive medical database (history, physical examination and laboratory testing as indicated) should be completed prior to provision of a diaphragm.
- B. Diaphragm Fitting:
  - 1. The diaphragm should fit comfortably with the anterior rim lodged behind the pubic bone and the posterior rim seated deep in the posterior vaginal fornix.

2. The largest, most comfortable diaphragm that fits well should be chosen. It is essential to involve the patient in the evaluation of the fit of her Diaphragm. She should be asked to offer her impression of how easy or difficult removal is for each size, and if two diaphragms fit equally well, which one feels more comfortable.
  3. Following fitting of the diaphragm, sufficient time should be provided for the patient to practice insertion and removal.
  4. Use of a back-up method of contraception until the return visit, or until the patient is sure that the diaphragm is staying in place during intercourse should be advised.
- C. Guidelines for cleaning and disinfection of fitting sets must be followed (See package insert in fitting set).
- D. Delayed Exam
1. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment).
  2. The reason for the deferral of pelvic exam must be documented in the client's medical record.
  3. A complete history, height, weight and BP is required in the medical record.
  4. Written results of a physical exam done by another provider within the last 12 months are acceptable.
  5. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. Pap test screening protocols for the site must be followed.

#### V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a diaphragm should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to diaphragms, including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Instruction on care of diaphragm (cleaning and inspection)
- D. Information that the diaphragm may provide only limited protection against STIs/HIV
- E. Method specific informed consent
- F. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- G. Written and verbal instruction on method use (may use Package Insert)
- H. Upon request, a copy of the method specific consent form
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

#### VI. PRESCRIBING DIAPHRAGM

Diaphragm size will be determined by the clinician after examining the client and fitting for size.

## VII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

- A. Recurrent vaginal or introital irritation, with no evidence of vaginal infection, may indicate an allergy or sensitivity to spermicide, latex, or silicone.
- B. Recurrent UTIs – consider method change.
- C. Toxic Shock Syndrome (TSS) signs or symptoms require urgent and intensive evaluation and treatment.
- D. Because TSS risk is increased for a woman who has had TSS in the past, the woman should avoid use of vaginal barrier methods in the future.

## VIII. FOLLOW UP

- A. The diaphragm user should be advised to return (at each of these visits diaphragm fit should be reassessed):
  - 1. In 2-3 weeks for a re-check of diaphragm fit, to evaluate placement skills and to screen for possible problems.
  - 2. Annually, or more often as requested by the client.
- B. Diaphragm fit also should be reevaluated in the case of:
  - 1. Frequent dislodgment.
  - 2. Vaginal or lower abdominal discomfort coincident with diaphragm use
  - 3. Full term pregnancy.
  - 4. Pregnancy termination after the first trimester.
  - 5. Pelvic surgery.
  - 6. Recurrent lower urinary tract infection.
  - 7. Weight gain or loss of 10 pounds or more.

## IX. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Diaphragms dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

## REFERENCES

- 1. CDC. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
- 2. Hatcher, R., et. Al. Contraceptive Technology. 19<sup>th</sup> Edition., 2007

## CLIENT EDUCATION FOR DIAPHRAGM

Before using the diaphragm, you need to know the possible disadvantages, risks, and warning signs to watch for. It is important that you read the manufacturer's package insert. You will receive information about the use, effectiveness, advantages, disadvantages, risks, and warning signs of other methods. We are happy to answer any questions you may have.

The diaphragm is a barrier method of birth control.

The diaphragm is made of latex or silicone and is dome-shaped. It is used with a spermicidal cream or jelly. It is inserted into the vagina and fits over the cervix. Of 100 women using the diaphragm, 16 will become pregnant during the first year of use. With consistent and correct use, this drops to 6.

The diaphragm offers limited protection against STIs. Since it covers the cervix, it may protect the cervix from direct contact with bacteria and viruses. Condoms are always the best way for sexually active individuals to reduce the risk of STIs. Diaphragms and condoms can be used at the same time.

### **To Increase Diaphragm Effectiveness:**

- Use it every time you have vaginal intercourse.
- Use contraceptive cream or jelly with every act of vaginal intercourse or if 6 hours or more has passed since the spermicide cream or jelly was inserted (even if no intercourse occurred)
- Use back-up method if more than one act of intercourse while diaphragm is in
- Leave the diaphragm in place for at least 6 hours after the last act of intercourse.
- Check diaphragm before each use for holes or weak spots.

### **Advantages of the Diaphragm**

- It can be left in place for up to 24 hours (but should not be left in place for longer than 24 hours)
- It is non hormonal.
- No effect on menstrual cycle.

### **Disadvantages of the Diaphragm**

- May have an allergic reaction to the latex or spermicide.
- May develop a bladder infection.
- May find it difficult to insert or remove.
- May be pushed out of place during intercourse.

### **You should not use the diaphragm if you have had, now have or develop in the future:**

- Allergy to the products.
- HIV/AIDS or high risk for HIV.
- History of toxic shock syndrome.

### **Warning Signs – notify the clinic or your health care provider if you experience:**

- Discomfort with diaphragm in place.
- Vaginal itching or irritation.
- Frequent bladder infections.
- Unusual vaginal discharge.
- Vulva/vaginal redness or swelling.

**Sign or symptoms of toxic shock syndrome (rare). *\*If you have these symptoms, remove the diaphragm and seek immediate care.***

- Sudden high fever.
- A sunburn-like rash.
- Diarrhea or vomiting.
- Sore throat.
- Aching muscles and joints.
- Dizziness, faintness, weakness.

**Return to the clinic to determine if the diaphragm still fits after:**

- A delivery.
- Pelvic or abdominal surgery.
- An abortion or miscarriage.

#### **Nonoxynol-9**

- In order for the diaphragm to be effective, it must be used with a spermicidal cream or jelly. Most include the spermicide nonoxynol -9 (N-9).
- It was hoped that N-9 would reduce the risk of STIs, including HIV, but the studies show that it offers no protection against STIs. Using N-9 many times a day may actually increase the risk of the infections.

**Regular physical exams for routine health care and for screening for STIs and cancer are strongly recommended for all sexually active women and men.**

## CONSENT FOR DIAPHRAGM

I, (print or type name) \_\_\_\_\_,  
request the diaphragm as my family planning method.

- I have received and read information about the diaphragm in the Patient Package Insert about the benefits, risks of using this method. I was given an opportunity to ask questions about all forms of birth control, meaning all prescription, non-prescription, and natural methods. All of my questions were answered to my satisfaction and I understood all of those answers.
- I understand that no method of birth control, except abstinence, is 100% effective against pregnancy or contracting sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV) infection I understand the diaphragm offers limited protection from sexually transmitted infections and that I need to use condoms for protection from these infections.
- I understand that the diaphragm is a barrier method of birth control, made of latex or silicone is dome shaped and is inserted into the vagina and fits over the cervix. It works by blocking sperm from entering the cervix.
- I understand the instructions for care and cleaning of the diaphragm.
- I understand that of 100 women using the diaphragm, 16 will become pregnant during the first year of use. With consistent and correct use, this drops to 6.
- I understand that in order to increase Diaphragm effectiveness I must:**
- Use it every time I have vaginal intercourse
  - Use contraceptive cream or jelly with every act of vaginal intercourse
  - Use back-up method if more than one act of intercourse while diaphragm is in
  - Leave the diaphragm in place for at least 6 hours after the last act of intercourse
  - Check diaphragm before each use for holes or weak spots
- I understand that the advantages of the diaphragm are as follows:**
- It can be left in place for up to 24 hours
  - It is non hormonal
  - No effect on menstrual cycle
- I understand that the disadvantages of the diaphragm are as follows:**
- I may have an allergic reaction to the latex or spermicide
  - I may develop a bladder infection
  - I may find it difficult to insert or remove the diaphragm and/or spermicide
  - It may be pushed out of place during intercourse
- I understand that I should not use the diaphragm if I have had, now have or develop in the future:**
- Allergy to the products that the diaphragms or spermicide are made of
  - HIV/AIDS or high risk for HIV

- History of toxic shock syndrome

**I will notify the clinic or my health care provider if I experience:**

- Discomfort with diaphragm in place
- Vaginal itching or irritation
- Frequent bladder infections
- Unusual vaginal discharge
- Vulva/vaginal redness or swelling

**I will remove the diaphragm and seek immediate care if I develop signs and symptoms of Toxic Shock Syndrome:.**

- Sudden high fever
- A sunburn-like rash
- Diarrhea or vomiting
- Sore throat
- Aching muscles and joints
- Dizziness, faintness, weakness

**I will return to the clinic to determine if the diaphragm still fits after:**

- A delivery of an infant
- Pelvic or abdominal surgery
- An abortion or miscarriage

I understand that most of the spermicides that are used with the diaphragm contain Nonoxynol-9 and that studies have shown that N-9 multiple times in a day (more than two) can increase the risk of infection with sexually transmitted infections including HIV.

I understand that regular physical exams for routine health care and for screening for STIs and cancer are strongly recommended for all sexually active women and men.

Date: \_\_\_\_\_ Client Signature: \_\_\_\_\_  
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Please complete the following if interpretation of informed consent was required:

An interpreter was offered to the client.  yes  no

This form has been read to the client in the client's spoken language.  yes  no

Patient's Language (specify):

Interpreter's Name: (print or type name of interpreter)

Interpreter Services provided by(agency):

Date: \_\_\_\_\_ Interpreter Signature: \_\_\_\_\_  
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Staff Use Only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date:

Staff Signature:

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