

VAGINAL CONTRACEPTIVE RING

I. INTRODUCTION

Oral contraceptive pills are very popular and effective, but poor compliance results in a significant rate of pregnancy. The vaginal contraceptive ring was developed to provide a similar, reversible contraceptive with a more convenient dosing schedule that would enhance patient compliance and achieve high contraceptive efficacy.

NuvaRing® is a soft, flexible, transparent ring measuring 54 mm diameter and cross-sectional diameter of 4 mm. It is made of ethylene vinyl acetate copolymers and releases 15 mcg ethinyl estradiol and 120 mcg etonogestrel per day in a steady low rate while in place and releases less estrogen daily than contraceptive pills or patches. In the unlikely event of damage to the ring, leakage or higher release of hormones does not occur, because the progestin and estrogen are mixed in the ethylene vinyl acetate core.

The primary mechanism of action is inhibition of ovulation. In addition, the vaginal contraceptive ring produces an endometrium that is not receptive to ovum implantation, and cervical mucus that becomes thick and hostile to sperm transport. Tubal and endometrial motility are slowed.

Perfect use failure rate in the first year of use: 0.3%

Typical use failure rate in the first year of use: 8%

Patients using NuvaRing should receive counseling about and, as needed, prescriptions for emergency contraception.

II. VAGINAL CONTRACEPTIVE RING DOSING SCHEDULE

A. Standard

1. Each ring is to remain in the vaginal for 3 weeks.
2. A new ring must be inserted 1 week after the prior ring was removed in order to have pregnancy protection.

B. Extended Regimen (Off-Label Use)

1. The continuous use of the contraceptive ring is effective for contraception.
2. The ring must be changed every 3 weeks; a new ring is immediately inserted after the old ring is removed.
3. Any ring-free interval cannot exceed 7 days.
4. Clients must be counseled that the more periods they skip, the more spotting they will have.
5. Extended regimen requires dispensing an extra ring for every 3 months of use.

III. CLIENT SELECTION

Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for vaginal contraceptive ring use.

- A. Appropriate candidates for vaginal contraceptive ring use include:
 - 1. Any client who meets criteria for any of the estrogen/progestin contraceptives.
 - 2. Any client who cannot remember to take the pill, deal with the patch, does not like shots or use local contraception at the time of intercourse.
- B. Consider the precautions prior to prescribing combined oral contraceptives (Appendix C). Refrain from providing combined oral contraceptives to those with major risk factors and use caution in prescribing for those with relative risk factors.
- C. In healthy clients over age 35 or those with a family history or premature death from cardiovascular disease, it is desirable to obtain a lipid profile and fasting blood sugar prior to prescribing combined oral contraceptives. If that is not feasible, those tests can be obtained at the time the next pill supply is given.
- D. Be cautious in prescribing combined oral contraceptives for clients with oligomenorrhea or amenorrhea. They may be infertile. Unless such a client's diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
- E. The ADA recommends that health care providers consider screening patients at 3-year intervals beginning at age 45, particularly in those with BMI ≥ 25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipidemia.
- F. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.
- G. The vaginal contraceptive ring may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormone contraceptive while breastfeeding. For non-breastfeeding clients the vaginal contraceptive ring may be initiated at 4 weeks postpartum. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
- H. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)
- I. Evidence among healthy women suggests the vaginal contraceptive ring does not alter vaginal flora or cervical cytology. Limited evidence on women with low-grade squamous intraepithelial lesions found use of the ring did not worsen the condition. The vaginal contraceptive ring may not be suitable for clients with conditions that make the vagina more susceptible to infection or ulceration. The ring may not be suitable for women with significant pelvic relaxation, who are unable or unwilling to touch their genitalia, or who have vaginal obstruction.

IV. VAGINAL CONTRACEPTIVE RING METHOD INITIATION

- A. Patients starting on the vaginal contraceptive ring are not required to have a pelvic examination. Access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) the vaginal contraceptive ring. Quickstart improves compliance with starting the second month of contraceptive ring use, and may decrease risk of unintended pregnancy.
 - 1. The clinician must be reasonably certain the client is not pregnant.
 - 2. Insert the first ring on the day of the visit.
 - 3. A back-up method of contraception is recommended for 7 days.
 - 4. If the client is in need of emergency contraception (unprotected vaginal intercourse has occurred within the past 5 days), she should take both tablets of Plan B® at once on the visit day and start her ring no later than the next day.
 - 5. Her next menses may be delayed until she completes her first cycle of the ring.
 - 6. Quick start does not increase irregular spotting or bleeding.
- C. If no hormonal contraceptive use in the past month:
 - 1. A new ring may be inserted any time during the first 5 days of a normal menstrual cycle.
 - 2. A back-up method of contraception is recommended for 7 days.
- D. If switching from a combination oral contraceptive,
 - 1. A new ring may be inserted any time within 7 days after the last combined oral contraceptive tablet and no later than the day a new cycle of pills would have been started.
 - 2. No back-up contraception is needed.
- E. If switching from a progestin-only oral contraceptive,
 - 1. A new ring may be inserted any day of the month, but not skipping any days between the last pill and the first day of ring use.
 - 2. A back-up method of contraception is recommended for 7 days.
- F. If switching from a progestin-only contraceptive injection,
 - 1. A new ring may be inserted on the same day when the next contraceptive injection is due.
 - 2. A back-up method of contraception is recommended for 7 days.
- G. If switching from a progestin-only contraceptive implant,
 - 1. A new ring may be inserted on the same day as the implant removal.
 - 2. A back-up method of contraception is recommended for 7 days.
- H. If switching from a progestin-containing IUD,
 - 1. A new ring may be inserted on the same day as the IUD removal.
 - 2. A back-up method of contraception is recommended for 7 days.
- I. Following a complete first trimester abortion or miscarriage,
 - 1. A new ring may be inserted within 5 days and no back-up contraception is needed.
 - 2. If not inserted within 5 days, a new ring should be inserted during the first 5 days of the next menstrual period. A back-up method of contraception is recommended for the first 7 days of ring use.
- J. Following a second trimester abortion:

1. A new ring may be inserted immediately after the second trimester abortion.
 2. A back-up method of contraception is recommended for 7 days if the NuvaRing® is started a week or more after the abortion procedure.
- K. Following a delivery:
1. Women who breastfeed should not use NuvaRing®.
 2. For non-breastfeeding women:
 - a. In women who are <21 days postpartum, use of combined hormonal contraceptives should not be used (USMEC category 4).
 - b. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
 - c. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
 - d. Any other medical conditions should be taken into consideration when determining the safety of the contraceptive method.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a vaginal contraceptive ring should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
- E. Instruction on how to insert and remove the vaginal contraceptive ring (see section below and refer to Patient Package Insert).
- F. Instruction on what to do if ring is expelled or left in for longer than 3 week period. Additionally, for some situations the use of emergency contraceptive pills may be considered.
- G. Information that vaginal contraceptive ring does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- H. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- I. If vaginal contraceptive ring is being provided/prescribed, then CHC consent form should be reviewed and signed.
- J. If vaginal contraceptive ring is being provided/prescribed to a client with risk factors, then a Request for CHC for Women with Risk Factors form should be reviewed and signed.
- K. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- L. Emergency, 24-hour telephone number and location where emergency services can be obtained

M. Clinic access information

VI. INSTRUCTIONS FOR VAGINAL CONTRACEPTIVE RING INSERTION, REMOVAL AND STORAGE

A. General use instructions:

1. The vaginal contraceptive ring is inserted by the client and worn for 3 weeks out of every 4 weeks. Routine use of the vaginal contraceptive ring requires the insertion of a new ring every 4 weeks to allow for withdrawal bleeding. Extended regimen use of the ring is optional (off-label use).
2. Removal of the ring for sexual intercourse is not recommended, but efficacy is maintained if the ring is replaced within 3 hours.
3. Tampon use is acceptable.
4. Oil-based vaginal medications do not affect the effectiveness of the ring. Water-based spermicides such as nonoxynol-9 do not affect the hormone levels of the ring.

B. Vaginal ring insertion:

1. The client washes and dries her hands.
2. The ring is removed from its reclosable foil pouch. The pouch is kept for proper disposal of the ring after use.
3. Client position for ring placement are lying down, squatting, or standing with one leg up.
4. The ring is held between the thumb and index finger and the opposite sides of the ring are pressed together.
5. The folded ring is gently placed into the vagina. The exact position of the ring is not important for it to work.
 - a. Most women do not feel the ring in place.
 - b. If the ring is causing discomfort, it should be gently pushed farther into the vagina.
6. The ring is to remain in place for 3 weeks in a row.

C. Vaginal ring removal:

1. The ring should be removed 3 weeks after the insertion on the same day of the week as it was inserted.
2. The ring is removed by hooking in index finger under the forward rim or by holding the rim between the index finger and middle finger and pulling it out.
3. Put the used ring in the foil pouch and properly dispose of it in a waste receptacle out of the reach of children and pets. Do not discard it in the toilet.
4. The menstrual period will start in 2-3 days and may not be finished before the next ring is inserted.

VII. INSTRUCTIONS FOR MANAGEMENT OF INADVERTENT PROLONGED USE, EXPULSION OR PROLONGED RING-FREE PERIOD

A. Instructions for inadvertent prolonged use:

1. If the ring has been left in the vagina for an extra week or less (4 weeks or less),
 - a. Remove the ring and insert a new ring after a 1-week ring-free break.
 - b. No back-up contraception is needed.
2. If the ring has been left in the vagina for 4 or more weeks,

- a. Remove the ring and insert a new ring.
 - b. Pregnancy should be ruled out.
 - c. A back-up method of contraception must be used until a new ring has been in place for 7 days.
- B. Instructions for prolonged ring-free interval
- 1. If the ring-free interval has extended beyond 1 week:
 - a. The possibility of pregnancy should be considered.
 - b. A new ring may be inserted immediately.
 - c. A back-up method of contraception must be used until a new ring has been in place for 7 days.
- C. Instructions for inadvertent ring removal or expulsion
- 1. If the ring has slipped out or been removed from the vagina for less than 3 hours,
 - a. The client is still protected from pregnancy.
 - b. The ring can be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible, and at the latest within 3 hours.
 - c. No back-up method of contraception is needed.
 - 2. If the ring has been out of the vagina for more than 3 hours,
 - a. The client may not be adequately protected from pregnancy.
 - b. The ring can be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible.
 - c. A back-up method of contraception must be used until the ring has been place for 7 days in a row.

VIII. INSTRUCTIONS FOR VAGINAL RING CONTRACEPTIVE STORAGE AND DISPENSING

- A. Storage instructions:
- 1. Prior to dispensing to the client, NuvaRing should be refrigerated at 36-46°F.
 - 2. The client should store NuvaRing at room temperature, range 59-86°F for up to 4 months. Avoid direct sunlight or storing above 86°F.
 - 3. A client may refrigerate the ring if so desired, but it is not recommended unless the client's refrigerator has a working thermometer.
- B. Dispensing instructions:
- 1. Give the new NuvaRing client a 1- or 2-month supply (1 or 2 rings).
 - 2. Clients may receive a prescription for a one-year supply of NuvaRing.
 - 3. Remind patients that NuvaRing should be stored at room temperature, range 59-86°F away from direct sunlight. NuvaRing can be stored for up to 4 months, which is why it is recommended that NuvaRing be dispensed at a maximum of 3 rings at a time.
 - 4. Dispensing more than 3 rings at a time may be necessary – women should be reminded regarding possible decreased product effectiveness after 4 months of storage or after the expiration date on the packaging.
 - 5. The routine use of condoms is recommended when a back-up method of contraception is warranted.
 - 6. The routine use of condoms is recommended to decrease the risk of acquiring sexually transmitted diseases.

IX. FOLLOW-UP

- A. The client should return in 1-2 months for evaluation of ring continuation. The client should have a blood pressure check and be evaluated for side effects. The 3-month dispensing schedule of NuvaRing is then begun.
- B. Serious side effects that may warrant immediate consultation and discontinuation of vaginal contraceptive ring include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - 2. Pain in calf or leg
 - 3. Crushing chest pain or tightness in the chest
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - 5. Sudden partial or complete loss of vision
 - 6. Breast masses suspicious for potential malignancy
 - 7. Severe abdominal pain or tenderness.
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - 9. Jaundice

X. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.

- A. Minor side effects specific to the contraceptive ring are vaginal leukorrhea, vaginal infection and irritation. A wet mount and STD testing may be required for ruling out other causes of these symptoms.
- B. Other common side effects of all estrogen/progestin contraceptives including the contraceptive ring include nausea and vomiting, breast tenderness, headache, menstrual cramps, abdominal cramps and bloating, changes in appetite, nervousness, depression, weight changes, rash, irregular vaginal bleeding, and intolerance to contact lens.
- C. Since there is only one formulation of the contraceptive ring, the client must decide whether to tolerate a minor side effect or switch to another contraceptive.
- D. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, the vaginal ring should be removed immediately and further evaluation is warranted.
- E. Other reasons for stopping the contraceptive ring:
 - 1. If major surgery or immobilization for an extended period of time is contemplated, the client should discuss discontinuing the use of the contraceptive ring with her surgeon.
 - 2. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP >160-100 are reasons to discontinue the contraceptive ring and refer the client for medical evaluation.
 - 3. With evidence of severe clinical depression, stop the contraceptive ring and refer the client for psychiatric evaluation. For mild mood changes a different estrogen/progestin contraceptive may be offered.
- F. Any client with post-ring amenorrhea of more than 6 months should be referred for evaluation.

- G. With 28-day cycling, one missed period with a negative pregnancy test may be managed by reassurance or a change in estrogen/progestin contraceptive. After 2 or more missed periods the client should be examined. Consideration may be given to additional evaluation and/or a change in contraception.
- H. Any client desiring to become pregnant may be advised to use contraceptive ring until pregnancy is desired. Fertility may return immediately following discontinuation of the ring. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.

XI. DOCUMENTATION

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

REFERENCES

1. US Medical Eligibility Criteria for Contraceptive Use, 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th Edition. MMWR, May 28, 2010; Vol 59.
2. Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004
3. Hatcher RA, Ziemann M et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2004
4. Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva Switzerland, 2004
5. Speroff L, Darney P. A Clinical Guide For Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2005
6. NuvaRing® Package Insert. West Orange, NJ: Organon USA Inc., 2004
7. Westhoff, C., et al., Initiation of oral contraceptives using a quick start compared with a conventional start: a randomized controlled trial, *Obstet Gynecol.* 2007 Jun;109(6):1270-6.

APPENDIX A

POSSIBLE HEALTH BENEFITS OF THE VAGINAL CONTRACEPTIVE RING

The possible health benefits of the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis
11. Possible fewer sickle cell crises

APPENDIX B

POSSIBLE HEALTH RISKS OF THE VAGINAL CONTRACEPTIVE RING

The possible health risks of the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gall bladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use the vaginal contraceptive ring should be strongly advised not to smoke.

APPENDIX C

PRECAUTIONS IN PROVIDING THE VAGINAL CONTRACEPTIVE RING

The precautions in providing the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

Refrain from providing the vaginal contraceptive ring for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Vascular heart disease with complications
5. Severe hypertension ($\geq 160/100$ mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history of breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute hepatocellular disease with abnormal liver function
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Hypersensitivity to any component of the vaginal contraceptive ring
16. Smoking and over age 35
17. Migraine headaches (without aura) and age > 35
18. Migraine headaches (without aura) and other risk factors for cardiovascular events, such as smoking or hypertension.
19. Use prior to 3 weeks post-partum.

Exercise caution in providing the vaginal contraceptive ring for women with:

1. Severe headache without aura
2. Hypertension (mild, or controlled with medication)
3. Active gall bladder disease
4. Surgery or injury requiring immobilization
5. Hyperlipidemia or history thereof
6. Lactation
7. Amenorrhea or oligomenorrhea (prior to evaluation)
8. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
9. Undiagnosed vaginal/uterine bleeding

APPENDIX D

DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include:

1. Barbiturates (Phenobarbital)
2. Griseofulvin
3. Rifampin
4. Phenylbutazone (Butazolidin®)
5. Primidone (Mysoline®)
6. Phenytoin (Dilantin®)
7. Carbamazepine (Tegretol®)
8. Felbamate (Felbatol®)
9. Oxcarbazepine (Trileptal®)
10. Topiramate (Topamax®)
11. St. John's Wort
12. Anti-HIV protease inhibitors

CONSENT FOR NUVARING® - VAGINAL CONTRACEPTIVE RING

I, (print or type name) _____,
request the vaginal contraceptive ring as my family planning method.

I have received a pamphlet (included with each ring) that has information about the benefits and risks of the vaginal contraceptive ring and how to properly use the ring.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the ring (8 out of every 100 women during the first year of typical use).

I understand the ring will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the ring to decrease the effectiveness of the ring. I know it is important to tell all my health care providers that I am on the ring.

I understand that when using the ring, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the ring:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the ring include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods
- Vaginal discharge

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR NUVARING – VAGINAL CONTRACEPTIVE RING was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____