

Prentif™ Cavity-Rim Cervical Cap

PATIENT PACKAGE INSERT

Instructions for use of the Prentif™ Cavity-Rim Cervical Cap for Contraception.

DESCRIPTION

The Prentif™ Cavity-Rim Cervical Cap is a small, flexible, cup-like device made of natural rubber and designed to fit closely around the base of the cervix. The device is 1 1/4 - 1 1/2 inches long with a firm, flexible rim at the open end. The device has a narrow groove along the inner surface of the rim which creates a seal when it is placed over the cervix. The device is currently available in four sizes: 22mm, 25mm, 28mm, and 31mm, as measured across the internal rim diameter.

ACTIONS

The Prentif™ Cavity-Rim Cervical Cap has a narrow groove along the inner surface of the rim which creates a seal when the cap is placed over the cervix, thus providing a physical barrier to prevent sperm from entering the cervical canal and fertilizing the egg. The cervical cap also holds a spermicide cream or jelly which is intended to kill any sperm that manage to swim around the rim of the cap. Thus, when used in conjunction with a spermicide cream or jelly, the Prentif™ Cavity-Rim Cervical Cap forms an effective barrier which prevents pregnancy. The cap must be left in place for a minimum of 8 hours after the last act of intercourse and may be left in place for a maximum of 48 hours (2 days). Insertion of additional spermicide with repeated acts of intercourse while the device is in place is not required.

INDICATIONS (USES)

The Prentif™ Cavity-Rim Cervical Cap is indicated for use by women of childbearing age as a barrier method of contraception. It is used in conjunction with a spermicidal cream or jelly to prevent pregnancy and must be left in place for a minimum of 8 hours after the last act of intercourse and may be left in place for a maximum of 48 hours (2 days).

CONTRAINDICATIONS (REASONS NOT TO USE)

Use of the Prentif™ Cavity-Rim Cervical Cap is contraindicated in the presence of any of the following conditions:

1. Inability to be properly fitted with the device.
2. Inability to insert or remove the device correctly.
3. Inability to understand instructions of use.
4. History of toxic shock syndrome (TSS).
5. Known or suspected uterine or cervical malignancy including unresolved, abnormal Pap smear.
6. Current vaginal or cervical infections.
7. During the menstrual period.
8. During the post-partum or postabortal period.

WARNINGS

If burning or irritation of the male or female genitalia is experienced during use, discontinue use and consult your physician or health practitioner.

PRECAUTIONS

To ensure effectiveness, the Prentif™ Cavity-Rim Cervical Cap *must* be left in place for at least 8 hours after the last act of intercourse.

The Prentif™ Cavity-Rim Cervical Cap *must not* be left in place for more than 48 hours (2 days) at a time.

Vaginal medications often contain petroleum products. Use of these with the cervical cap may cause the latex rubber to deteriorate. Do not use the cap until the vaginal treatment is complete.

Use of the Prentif™ Cavity-Rim Cervical Cap is contraindicated during menstrual bleeding. An alternate form of contraception should be used if intercourse is desired at this time.

Use of the Prentif™ Cavity-Rim Cervical Cap is contraindicated during the post-partum period (within 6 weeks of childbirth). Because the size of the cervix may change as a result of childbirth, the user should visit her physician or health practitioner for an examination and refitting of the cervical cap before resuming use of this method after childbirth, miscarriage, or other termination of pregnancy.

To date, an association has not been established between cervical cap use and Toxic Shock Syndrome (TSS); however, this remains a possibility. Symptoms of TSS include sudden high fever (usually 102 degrees 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 you experience a high fever and one or more of other TSS symptoms, remove the cervical cap and contact your physician immediately.

ADVERSE EFFECTS

Potential adverse effects of the cervical cap may include: pregnancy; discomfort during use, vaginal or cervical infection; cervicitis; laceration of the vagina, cervix, or penis; abnormal Papanicolaou (Pap) smear; and allergic reaction to the cap material or spermicide.

POSSIBLE PROBLEMS AND WHAT TO DO

A physician or health practitioner should be consulted if any of the following occur:

1. Difficulty inserting or removing the device.
2. Uncertainty about proper placement.
3. Discomfort is experienced by you or your partner.
4. The device becomes dislodged during intercourse or when you walk, cough or strain.
5. The device no longer fits snugly around the base of the cervix.
6. If at times other than onset of menstruation, blood is noticed in the device upon removal.
7. If there are any holes, tears, cracks, or other deterioration of the device.
8. If pain or discomfort is experienced after inserting the device, or during or after intercourse.
9. If vaginal odor or odor within the device is noticed.
10. If unusual vaginal discharge is observed.

ROUTINE FOLLOW-UP EXAMINATIONS

Is it advised that you revisit your physician or health practitioner:

1. After the first 3 months of wear for a Pap smear and evaluation of device fit. A repeat Pap smear after 3 months of cap use is extremely important because an increased proportion of cap users compared to diaphragm users experienced an abnormal change in Pap smear at this interval during the clinical study of the device. If your Pap smear becomes abnormal you must discontinue use of the cap and consult your physician.
2. Every 12 months for a gynecological examination, Pap smear, and new fitting of the Prentif™ Cavity-Rim Cervical Cap.
3. If signs of damage or deterioration of cap, such as holes, tears, or cracks are evident.
4. For an examination and refitting of the Prentif™ Cavity-Rim Cervical Cap after childbirth, miscarriage, or other termination of pregnancy.

EFFECTIVENESS

The Prentif™ Cavity-Rim Cervical Cap has been found to range in effectiveness from 82.6% - 93.6%, depending on consistency of use.

INSTRUCTIONS FOR USE

1. Proper placement of the cervical cap is essential for effectiveness.
2. Before inserting, the cervical cap should be filled one-third full with spermicidal cream or jelly.
3. The cervical cap must be left in place for a minimum of 8 hours after the last act of intercourse and may be left in place for up to 48 hours (2 days).
4. Insertion of additional spermicide with repeated acts of intercourse while the device is in place is not required.
5. The cervical cap *should not* be removed to apply additional spermicide.

INSERTING THE CERVICAL CAP

1. Urinate and wash your hands before inserting the cap.
2. Examine the cap to make sure there are no holes, tears, cracks, or other signs of wear.
3. Fill the cap one-third full with spermicidal cream or jelly. Unlike the diaphragm, with the cervical cap there is no need to apply spermicide to the rim prior to insertion.
4. Find the position in which you feel most comfortable for inserting the cap. Squatting or standing with one foot up on a chair is usually best.
5. Locate your cervix with your finger. It will feel like a short, hard nose projecting into the vagina.
6. Separate the lips of your vagina with one hand and with the other squeeze the rim of the cap between the rim of the cap between your thumb and index finger.
7. Slide the cap into your vagina, and push it inward along the rear wall of the vagina as far as it will go. Using your finger to locate the cervix, press the rim of the cap around the cervix until it is completely covered.
8. Check that the cap is properly in place by pressing the dome of the cap with your index finger to make sure the cervix is covered. Then sweep your finger around the rim of the cap. The cervix should not be felt outside the cap.
9. If the cap is not in the correct position, either push it onto the cervix or remove and reinsert it.
10. The cervical cap is designed to cover the cervix, but the cervix will not completely fill the dome of the cap. The additional space is for holding spermicide and cervical secretions.

REMOVING THE CERVICAL CAP

1. Wash your hands before removing the cap.
2. At least 8 hours should have elapsed since your last act of intercourse before you remove the cap.
3. Douching is not recommended prior to cap removal.
4. To remove the cap, find the position that is most comfortable for you. Usually, squatting or standing with one foot up on a chair works best.
5. Remove the cap by pressing on the rim of the cap with your finger until the seal is broken and you can tilt the cap off the cervix.
6. Once you have broken the seal, ease your fingertip over the rim of the cap and pull it sideways out of the vagina.
7. If you are having difficulty breaking the seal, squat and bear down as if you are having a bowel movement while trying to break the seal.

CLEANING AND STORAGE

The Prentif™ Cavity-Rim Cervical Cap should be thoroughly cleaned after each use by washing with a mild, unperfumed soap and warm water. The cap should be rinsed thoroughly in clean water and then dried carefully. The cap should be stored in its original or other suitable, clean container between uses. Storage in a cool, dry place, protected from light, is recommended.

Except for mild, unperfumed soap, the Prentif™ Cavity-Rim Cervical Cap should not be used with any cleaning products not made or specifically recommended for use with the cap.

The Prentif™ Cavity-Rim Cervical Cap should not be used with oil-based lubricants or greasy substances, such as cocoa butter, cold cream, petroleum jelly, mineral oil, or vegetable oil, which may cause rapid deterioration of the rubber.

HOW SUPPLIED

Each Prentif™ Cavity-Rim Cervical Cap is individually packaged in a small, sturdy carton. The outer carton is marked with the cap size and manufacturing batch number. The Prentif™ Cavity-Rim Cervical Cap is currently available in four sizes: 22mm, 25mm, 28mm, and 31mm, as measured across the internal rim diameter.

The Prentif™ Cavity-Rim Cervical Cap is distributed exclusively in the United States of America by:

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