

Prentif™ Cavity-Rim Cervical Cap

Fitting Instructions

The Prentif™ Cavity-Rim Cervical Cap is a barrier method of contraception, used in European family planning clinics for many years. In common with other barrier methods of birth control, the popularity of the Prentif™ and other cervical caps declined with the introduction of the contraceptive pill and intrauterine devices (IUDs). Now, as women and their physicians and health practitioners have become more aware of the dangers inherent in the newer methods, cervical caps are once again becoming a more popular choice.

The Prentif™ Cavity-Rim Cervical Cap is made in England and was first introduced into the UK market around 1930, where it has been used in Family Planning Clinics ever since. It is also used in France, Germany, Switzerland, Belgium, South Africa, Israel, Australia, New Zealand, and Canada. The Prentif™ Cavity Rim Cervical Cap was tested clinically in the United States as an investigational device beginning in 1980. In a major clinical study sponsored by the National Institute of Child Health and Human Development (NICHD), in which the Prentif™ Cavity-Rim Cervical Cap was compared to the diaphragm, the cervical cap was found to be similar to the diaphragm in its effectiveness in preventing pregnancy. The available studies provide reasonable assurance that the Prentif™ Cavity-Rim Cervical Cap is a safe and effective method of birth control. A pre-market approval application (PMA) for this device has now been approved by the FDA enabling the device to be marketed in the United States.

Suitability of Patients

Most women are potentially suitable to use the Prentif™ Cavity-Rim Cervical Cap, however, use of the cap is contraindicated in the presence of any of the following conditions:

- Inability to be properly fitted with the device.
- Inability to insert or remove the device correctly.
- Inability to understand instructions for use.
- History of toxic shock syndrome (TSS).
- Known or suspected uterine or cervical malignancy including unresolved, abnormal Pap smear.
- Current vaginal or cervical infections.
- During the menstrual period.
- During the postpartum or postabortal period.

Fitting the Patient

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. Before fitting a patient with the Prentif™ Cavity-Rim Cervical Cap, the patients should be given a thorough gynecological examination and Pap smear to determine her suitability to use the cervical cap.

Fitting the Patient (continued..)

A gonorrhea culture and vaginal smear, to check for asymptomatic infections or to identify visible symptoms, should be performed when indicated. Women with contraindications to cap use should not be fitted with the device. The following procedure is recommended:

1. Have the patient empty her bladder.
2. Insert an appropriately sized speculum in the vagina and bring the cervix into view.
3. Note the size and shape of the cervix.
4. Estimate which cap is likely to be needed.
5. Note if any nodules, lesions, cysts or other abnormalities are present.
6. Remove the speculum and do a bimanual exam to determine: (a) uterine size and position, (b) position of the cervix, and (c) length and diameter of the cervix.
7. Several different sizes from the cervical cap fitting set should be placed on the cervix to determine the best fit. Start with the size you think will most likely fit.
8. Squeeze the sides of the rim together and hold the cap with the dome pointing downward. A small amount of lubricant may be applied to the outside of the rim to facilitate insertion.
9. Separate the labia and gently insert the cap into the vagina and guide into place with one or two fingers until it covers the cervix.
10. The cap should cover the cervix, adhere to the cervix firmly, and not be dislodged during the digital exam while checking for placement of the cap. Fit with the smallest size possible.
11. To remove the device, push the rim away from the cervix with one or two fingers to break the suction and gently pull the cap out of the vagina.
12. Cervical cap fitting sets should be disinfected by soaking in an aqueous bleach solution (3 parts water: 1 part bleach) for a minimum of 20 minutes. After disinfection, the caps should be thoroughly washed with soap and water prior to reuse.

Judging the Cap Fit

A properly fitted Prentif™ Cavity-Rim Cervical Cap should entirely cover the cervix, with the rim of the cap tucked snugly and evenly into the fornix (the conjunction of the vaginal walls and the cervix at the back of the vagina). No gaps should exist between the rim and the cervix and the cap should not be able to be easily dislodged by the fitter. After the cap is in place, there are several maneuvers that can be performed to evaluate fit:

Judging the Cap Fit (continued..)

1. Make a full 360-degree sweep of the cap rim, searching for gaps or exposed parts of the cervix.
2. If a gap is found, see if the rim pulls away easily.
3. After the cap has been in place for a minute or so, check the suction by pinching the excess rubber of the dome between the tips of two fingers and tug. The dome should be collapsed. (This step is more difficult with the stiffer 22mm and 25mm sizes)
4. Attempt to dislodge the cap by gently pushing and tugging on it with one or two fingers from several angles, being careful not to hurt the patient.

Patient Instructions

The Prentif™ Cavity-Rim Cervical Cap depends for its effectiveness on scrupulous instruction by the physician or health practitioner. Careful initial instruction is essential to ensure that the new user benefits from effective day-to-day use. After a little practice most women should be able to insert the Prentif™ Cavity-Rim Cervical Cap quickly and effectively. Each step of the following procedure should be carefully explained to the patient and mastered by her before proceeding to the next step. The patient also should be provided with a copy of the user's guide, entitled "The Prentif™ Cavity-Rim Cervical Cap for Contraceptive Use - Information for Patients", supplied by Lamberts (Dalston) Limited, which provides detailed instructions on proper use and care of the cap.

1. Instruct the patient to wash her hands.
2. Instruct the patient to find her cervix by exploring the vagina while in a squatting position or with one foot up on a chair.
3. Instruct the patient to practice fitting the cap over the cervix. This may be most comfortable for the patient in a squatting position, or standing with one foot up on a chair, or in another position which she finds comfortable.
4. Instruct the patient to separate the labia of the vagina with one hand while squeezing the rim of the cap between thumb and forefinger.
5. The patient should slide the cap into the vagina and push it as far along as it will go before pressing the rim into position around the cervix with the forefinger.
6. Instruct the patient to check the placement of the cap by attempting to feel the cervix through the rubber.
7. Repeat the process until all steps can be completed easily and effectively.

Patient Instructions (continued..)

8. It is highly recommended that the patient allow at least a week of practice, using condoms or other method as a backup contraception, before relying on this method of contraception. During this time, the patient should carefully check cap placement before and after intercourse to make sure that the cap remains properly in place during intercourse. If dislodgment occurs, the patient should discontinue further use of the cap and return to her physician or health practitioner for consultation. It may be that a different size cap or further instruction on inserting the cap is required.
9. Instruct the patient to return in three months for a Pap smear and evaluation of device fit.

Instructions for Patients

The following instructions should be explained to any patient receiving a Prentif™ Cavity-Rim Cervical Cap for contraceptive use.

1. When relying on this method of contraception, the cap should be filled with spermicidal cream or jelly until it is about one-third full.
2. The cap should be inserted prior to intercourse and must be left in place a minimum of 8 hours after intercourse. The cap may be left in place for up to 48 hours (2 days) at a time.
3. If intercourse takes place more than once, it is not necessary to insert additional spermicide, however, the patient should check to make sure the cap is properly in place over the cervix before and after each act of intercourse.
4. After each use, the cap should be washed carefully with a mild, unperfumed soap and warm water, and then dried. Storage in a cool, dark place is recommended.
5. The cap should not be worn during the menstrual period. An alternate form of contraception should be used during this time if intercourse is desired.
6. The Prentif™ Cavity-Rim Cervical Cap should not be used during the postpartum period (within 6 weeks of childbirth). The patient should visit her physician or health practitioner for an examination and refitting of the cervical cap before resuming this method after childbirth, miscarriage, or other termination of pregnancy.

Routine Follow-Up Examinations

The patient should be advised to revisit her physician or health practitioner:

1. After the first three months of wear for a Pap smear and evaluation of device fit. A repeat Pap smear after three months of cap use is extremely important because an increased proportion of cap users compared to diaphragm users experienced Pap smear conversions from Class I to Class III at this interval during the clinical study of the device.

Routine Follow-Up Examinations (continued..)

If the patient's Pap smear converts from normal to abnormal she must be advised to discontinue use of the cap.

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 the 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.

If Problems Occur

The patient should be encouraged to contact her physician or health practitioner any time she has problems or questions about the use of the device or if any of the following occur:

1. The patient experiences difficulty inserting or removing the device.
2. The patient is uncertain about proper placement of the device.
3. The patient or her partner feels or is made uncomfortable by the presence of the device.
4. The device becomes dislodged during intercourse or when the patient walks, coughs, or strains.
5. The device no longer fits snugly around the base of the cervix.
6. If at times other than onset of menstruation, the patient notices blood in the device when it is removed.
7. The patient notices any holes, tears, cracks or other deterioration of the device.
8. The patient experiences pain or discomfort after inserting the device, or during or after intercourse.
9. The patient experiences unpleasant vaginal odor or odor within the device.
10. The patient experiences an unusual vaginal discharge.

Warnings

The patient should be advised of the following:

Except for mild unperfumed soap, the Prentif™ Cavity-Rim Cervical Cap should not be used with any

Warnings (continued..)

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.

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 F or more), vomiting, diarrhea, dizziness, fainting or near fainting when standing up, or a rash that looks like a 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 other TSS symptoms, remove the cervical cap and contact your physician immediately.

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

Lamberts

Lamberts (Dalston) Limited of Luton, England is a well established company and the sole manufacturer of the Prentif™ Cavity-Rim Cervical Cap. For more than 50 years they supplied contraceptive caps to the great pioneer of modern birth-control in the United Kingdom, Marie Stopes, and in fact took over her very first clinic when she moved on to the second. Lamberts continued to run the clinic in Holloway, London until 1975.

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