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Barrier Contraceptives

Male Condoms, Vaginal Spermicides, and Cervical Barrier Methods

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MALE CONDOMS

Latex condoms, when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS (1).

Introduction

Male condoms are a popular contraceptive method. Additionally, they also play an integral role in US public health programs designed to prevent the spread of HIV and other sexually transmitted infections (STIs). Since the 1986 report from the US Surgeon General advocating the use of condoms to help prevent the spread of AIDS, awareness of the benefits of condom use has continued to increase. The percentage of reproductive-age women choosing condoms for contraceptive protection increased from 13% in 1988 to around 20% today. Use among sexually active adolescents is dependent on a variety of factors, including race and ethnicity, but averages around 45% (2,3).

Although correct and consistent use of the male latex condom reduces the risk of HIV and STI transmission in at-risk persons, no method is 100% effective. The best way to avoid transmission of STIs is to abstain from sexual intercourse or to be in a long-term, mutually monogamous relationship with a partner who is known to be uninfected.

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Effectiveness

CONTRACEPTIVE EFFICACY

- The male condom prevents pregnancy by acting as a physical barrier to sperm movement and is most effective if used from “beginning to end” on every sexual contact.

If used correctly on each act of sexual intercourse, only about 2–3% of couples will experience unintended pregnancy during the first year of use. However, typical first-year failure rates are about 15% because many couples fail to use condoms with each act. Both US consumer surveys (4) and tightly controlled trials (5) document that couples using condoms for their sole method of contraception report using condoms correctly and consistently in less than 50% of cycles.

PROTECTION FROM STIs AND HIV

- In vitro studies show that latex condoms are impermeable to a large number of bacterial and viral STIs, including HIV (6).
- Genital areas not covered by the condom, improper or inconsistent use of the condom, or damage to a condom are factors that may allow viral or bacterial transmission.

Several clinical studies of heterosexual couples who consistently used latex condoms to prevent transmission of HIV from an infected individual to their non-infected partner, reported around a 90% success rate (7,8). A meta-analysis of 25 studies report efficacy rates for condoms preventing the transmission of HIV ranging from 87 to 96% (9). The success rate of the condom’s ability to protect from transmission of other STIs have been more variable, but studies generally confirm reductions in gonorrhea, genital herpes, chlamydia, syphilis, and trichomoniasis (10–15).

Advantages of Male Condoms

- Effective at preventing pregnancy when used correctly and consistently.
- Compared with other barrier methods, the male condom is considered to be the most effective for prevention of the transmission of STIs and HIV.
- One of the most cost-effective contraceptive options now available, especially in view of the fact that condoms also offer protection against STI and HIV transmission (16). Prices vary from as low 25¢ per condom to more than \$1 in cost. Some publicly funded organizations offer condoms at very low or no cost to certain users.

B Latex condoms are generally the cheapest type.

- Relatively easy to get, easy to use, highly portable, and can be bought in a variety of stores without a prescription.
- Do not have systemic side effects.
- Offer better hygiene because the semen is collected and discarded with the condom following use.

Table 1
Oil-Based Products That May Degrade Latex Condoms,
Latex Diaphragms, or Cervical Caps

Vaseline petroleum jelly
Hand lotions
Cold cream
Baby oil
Peanut oil
Suntan oil
Corn or sunflower oil
Massage oil
Whipping cream
Vaginal yeast medications: Femstat [®] , Monistat [®] , Vagisil [®]
Estrogen cream

- By blocking the movement of gonorrhea and other STIs, female partners of users have a lowered risk of developing pelvic inflammatory disease and tubal-factor infertility (17).
- Provide some limited protection from spread of human papillomavirus (HPV) (18) and their use is associated with a lowered rate of cervical dysplasia and cancer (19).
 - B Although condoms do not appear to provide as much protection from HPV as from other STIs, the Centers for Disease Control and Prevention recommends condom use as a way to reduce the risk of HPV and herpes infections (20).
- During use, some men are able to sustain erection longer.
- Come in many sizes, colors, flavors, and styles.
 - B Available with and without ribbing, studs, and lubrication or spermicide.

Disadvantages of Male Condoms

- During vaginal or anal intercourse, condom breakage is reported to occur about 2% of the time.
- Although rates vary, condom slippage off of the penis occurs in about 2% of vaginal intercourse.
 - B Improper placement or incorrect withdrawal technique may increase this risk.
 - B Partial slippage during intercourse may allow skin-to-skin transmission and increased risk of STI transmission.
- Efficacy is compromised with re-use of a condom, inconsistent use, improper use, concomitant use of latex condom with oil-based lubricants or vaginal medications (Vaseline[®] [petroleum jelly], suntan oil, whipped cream, Crisco[®], baby oil, hand lotions, vaginal yeast medications, or massage oil; Table 1) (21).
 - B Polyurethane condoms are not affected by oil-based products.
 - B Condoms tear easily with fingernails, a ring, teeth, or anything sharp.

- Polyurethane condoms may be necessary in persons with latex allergies.
- The man must pull out soon after ejaculation.
 - B If the man loses his erection, the condom can fall off and protection is lost.
- Animal membrane condoms are not as effective at protecting against infection as latex or polyurethane condoms.

USER COMPLAINTS

- Unless the partner puts it on as a part of foreplay, the condom interrupts sex.
 - “It spoils the spontaneity” or alters the “mood.”
 - May imply a lack of trust.
- Fear that one may face rejection if he or she insists on condom use.
- Less sensation and pleasure.
- Difficult to use if the male partner is unable to maintain an erection.
- Embarrassment when purchasing condoms over the counter.

Patient Counseling

Unless a sexually active person is in a mutually monogamous relationship, they are at risk for the transmission of STIs and HIV/AIDS.

Condom use is strongly recommended for sexually active women and men who are not in mutually monogamous relationships. Dual use of a condom plus another contraceptive method, such as oral contraceptives, is the “gold standard” and is a good option for sexually active adolescents, young singles, or others at risk for STIs and unintended pregnancy.

Many of the problems experienced by condom users are usually resolved as users become more experienced. The different brands and types of condoms offer a variety of options and advantages. The counselor should encourage users to try different brands should problems develop.

- STIs impact millions of people in the United States each year, especially young people.
- Half of all people with HIV were infected before they were 25 years old.
- STIs can be painful, cause infertility, and lead to serious health problems, including death.
- STIs may be silent and unknown to the infected individual.
- Using condoms properly every time:
 - B Reduces the risk of STI and HIV/AIDS transmission.
 - B Reduces the risk of pregnancy.
 - B May protect the future fertility of the female.
- Condoms are designed to give pleasure, protection, and freedom from worry.
- There are many different styles of condoms, and they are easy to find in stores and easy to use.
- Using a water-based lubricant (such as Very Private® Intimate Moisture, Astroglide®, or MyPleasure® Personal Lubricant Gel) may decrease the risk of condom breakage.



Fig. 1. Ultra-lubricated male condom with a reservoir-tip and container pouch.

PATIENT COUNSELING TECHNIQUES

Be ready to explain the benefits of condom use to your partner.

A potential user should be ready to respond to any partner objections with the following statements about condom use:

- It is a smart thing to do.
- It is a responsible act that demonstrates maturity.
- It shows respect for a partner.
- It is evidence that the users care about the safety of others.
- It will improve the “mood” because both partners will feel more secure.

INSTRUCTIONS REGARDING PROPER USE OF CONDOMS

- Select an appropriate size and style of condom at a pharmacy. Note the expiration date and have condoms readily available.
- Before intercourse, discuss condom use with partner. Be ready to explain that condom use is smart, responsible, and will improve the “mood.”
- A new condom is used “beginning to end” for every act of intercourse.
- As soon as the penis is erect, open the package and compress the tip of the condom to remove any excess air. Check the condom to make sure it is not dried out or torn. Use another condom if damage is detected or if the condom appears old.
- Place the open end of the condom, ring side up, on to the head of the penis.
- Roll the condom down the shaft of the penis until the condom is completely unrolled. The condom should cover the entire shaft of the penis and fit smoothly. There should be a small space left or a reservoir tip at the tip for collection of semen (Fig. 1).

- Right after ejaculation, hold the top rim of the condom firmly against the still-erect penis and make sure it remains in place as the penis is withdrawn.
- The condom is removed after the penis is withdrawn.
 - B The condom is checked for holes or damage.
 - B If condom damage is noted or if slippage occurred during intercourse, consider emergency contraception (within 72 hours) and STI follow-up/treatment.
- Condom is disposed in a trash container.

Options

There are more than 100 different condoms on the US market today. A user can choose a condom with or without lubricants or spermicides, reservoir tip, and ribbing. They come in a variety of thicknesses, colors, sizes, shapes, and scents (including mint). The majority of condoms are made of latex (rubber-based), but they are also available in polyurethane (synthetic) or natural membrane (intestinal caecum of lambs). A unisex condom has also been introduced. The unisex condom is a modified condom that has a hoop at the base. It is made of a very thin, hypoallergenic plastic, and is designed to be used with a lubricant. It may be used by either women or men and is thinner than most latex condoms.

Newer model condoms made of polyurethane may be more comfortable, less constricting than latex condoms, and are not affected by oil-based lubricants. Polyurethane condoms offer similar protection against STIs and small viruses as latex condoms. The polyurethane condom is a good option for the 1% of the US population with a latex allergy (22). Some users prefer the soft, “natural” feel of the natural membrane condoms but these condoms contain small pores, and thus do not protect against HIV and STI transmission. The latex condoms tend to have the lowest cost.

With so many options available, dissatisfied users should be encouraged to shop around and try different types. Many of the problems encountered by condom users may be solved as they become more experienced and find the right condom.

Condoms are considered a medical device and regulated by the US Food and Drug Administration (FDA). Condoms must meet minimum thickness and width standards, and are periodically subjected to laboratory testing for leakage, strength, and packaging standards.

VAGINAL SPERMICIDES

Introduction

Vaginal spermicides are relatively inexpensive and available over the counter. Like other barrier methods, the contraceptive effectiveness of vaginal spermicides is highly dependent on the user’s ability to use the method consistently and properly. Spermicides are placed immediately before each sexual contact and effectiveness lasts only 1 hour. When used alone, vaginal spermicides may pro-

vide limited protection against the transmission of STIs and do not protect against HIV infection. They are most effective when used with other barrier methods, such as the male condom, diaphragm, or cervical caps.

Effectiveness

Vaginal spermicides, when used alone, have highly variable typical use failure rates that range from 5 to 50%. It is difficult to compare different spermicides because their effectiveness is highly dependent on the user's ability to use the method consistently and properly. Correct placement of the spermicide against the cervix and adequate time for dispersion are critical factors that may not always be fulfilled. Generally, failure rate for spermicides is around 20–30% for typical use and 6–18% for perfect use. Use of a spermicide with other barrier methods significantly increases effectiveness and is strongly recommended.

- Use of a spermicide with a condom is associated with a 1-year failure rate as low as 0.1%.

Advantages of Vaginal Spermicides

- Are low cost and available over the counter.
- Can be used by wide range of users and rarely have systemic effects.
- Are easy to transport and can be readily available.
- Can be a unilateral decision not requiring partner approval.
- May provide additional lubrication during intercourse.
- Can be used with a variety of other barrier methods.
- Are useful a variety of situations including:
 - B Temporary use while waiting to use another method.
 - B During breastfeeding.
 - B After missing two or more pills in a cycle.
 - B Suspicion that an intrauterine device has been expelled.
 - B Infrequent sexual activity.
 - B Mid-cycle to augment other methods.
- May provide some limited protection against gonorrhea and chlamydia.

Disadvantages of Vaginal Spermicides

- Lasts only 1 hour after insertion.
- Typical failure rates range from 20 to 30% (but are substantially reduced if vaginal spermicides used with other methods).
- Although nonoxynol-9 is lethal to many organisms, including trichomoniasis, chlamydia, syphilis, genital herpes, and HIV, clinical trials have reported mixed results regarding STI protection from use of vaginal spermicides (23–26).
 - B If used more than twice per day, spermicides may damage the vaginal mucosa and increased rates of HIV transmission are reported in some studies (27).

- Some users complain about the messiness, taste, necessity of having to touch the genitals, wait time necessary for the suppositories to dissolve, or excessive lubrication.
- Spermicide use can result in local vaginal and vulvar irritation, especially with frequent use. If an allergy or sensitivity is suspected, another contraceptive method should be considered.
- Use of spermicides is associated with higher rates of:
 - B Urinary tract infections (28).
 - B Vaginosis.
 - B Yeast vaginitis when used with a diaphragm.
- Although there is concern, several studies report no causal association between fetal defects and use of spermicides (29,30).
- Women with vaginal or uterine prolapse, or those with a vaginal deformity, such as a septum, are poor candidates because they may not be able to correctly place the spermicide.

Patient Counseling

One applicator or suppository is necessary for each act of intercourse and is effective for only 1 hour.

Vaginal spermicides are a good choice for women who are highly motivated to use the method properly and consistently on each sexual act. Use of vaginal spermicides with other barrier methods significantly improves contraceptive effectiveness. Women with risky sexual behaviors who are especially prone to STI exposure should use the vaginal spermicide plus a condom.

- User should read the product instructions.
- The spermicide must cover and coat the cervix to ensure contraceptive effectiveness.
 - B High placement in vagina near the cervix necessary.
 - B If a suppository, tablet, or film is used, it is necessary to wait at least 15 minutes to ensure adequate dispersion of the spermicide.
 - B Spermicide must be left in place for at least 6 hours after intercourse.
- No douching for at least 6–8 hours.
- Keep adequate supplies available.
- Women with a vaginal abnormality that may interfere with proper placement of the spermicide should check with a health care provider.
- If irritation occurs, changing to another product may be advisable.
- In case the spermicide is used incorrectly, emergency contraception should be considered.

PROPER USE OF VAGINAL SPERMICIDES

- Foam. The aerosol can must be shaken at least 20 times. The applicator is placed on top of the aerosol container and pressed down. This causes the applicator to fill with foam. The applicator is then inserted high into the vagina. At elevations

higher than 3500 ft, it is necessary to use two applicators. Contraceptive protection begins immediately and remains effective for 1 hour.

- Gel or cream. Open the tube. Place the open end of the applicator over the opening and squeeze the spermicide into the applicator. The applicator is then inserted high into the vagina near the cervix. The applicator is held still and the plunger is pushed to release the product. Contraceptive protection begins immediately and lasts up to 1 hour.
- Vaginal contraceptive film. Hands must be clean and dry before touching the film. A small thin sheet is removed from the wrapper, folded in half, and inserted as high as possible onto the back wall of the vagina. The film should rest on or near the cervix. Contraceptive protection begins 15 minutes after insertion and remains effective for about 1 hour.
- Suppository or tablet. The wrapper is removed and the suppository or tablet is inserted high into the vagina near the cervix. Contraceptive protection begins 10–15 minutes after insertion and remains effective for about 1 hour.

Options

Spermicidal preparations have two components: the base (gel, foam, cream, film, suppository, or tablet) and the spermicidal chemical that kills sperm.

Nonoxynol-9, a surfactant that disrupts the cell membrane of the sperm, is the active agent in most spermicidal products marketed in the United States. A few spermicides contain octoxynol. Other surfactants, available in other parts of the world include menfegol and benzalkonium chloride. Many new spermicidal products are under testing and evaluation.

Vaginal spermicides come in a variety of options including foam, film, suppository, tablets, coated latex condoms, creams, gels, and jellies (some of the available brands include Ortho-Gynol[®], Ortho-Cream[®], Gynol II[®], Preceptin[®], Kormex II[®], Conceptrol[®]).

CERVICAL BARRIER METHODS: COMPARISON OF THE DIAPHRAGM, FEMALE CONDOM, CERVICAL CAP AND SHIELD, AND VAGINAL SPONGE

Introduction

Cervical barrier methods are effective when they are used consistently and properly. They are popular with many women because they provide convenience, safety, and sexual spontaneity. Depending on the method, there are limited degrees of protection from STI and HIV transmission, although there is a growing body of research suggesting that covering the cervix may potentially play an important role. The contraceptive sponge was the largest-selling over-the-counter female contraceptive in the United States until it was abruptly taken off the market in 1995. Because of a high demand for its return, it was re-introduced in 2005.



Fig. 2. Side view of a diaphragm.

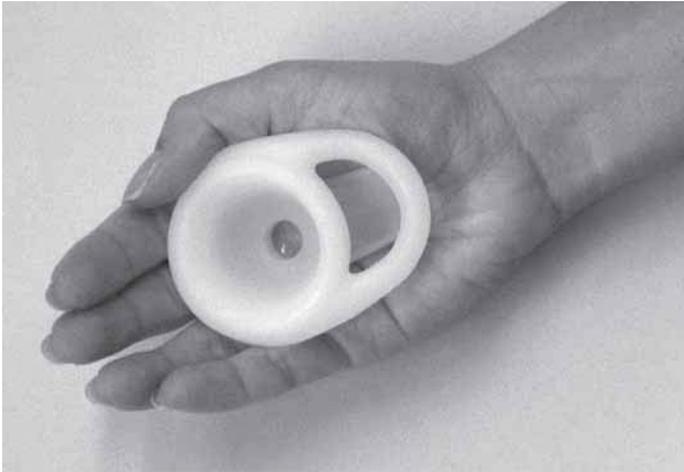


Fig. 3. Lea's Shield. (Reproduced with permission from Yama, Inc.)

The sponge and female condom are available over the counter. The female condom shares many of the same advantages and disadvantages as the male condom. The diaphragm is used with a spermicide, must be fitted by a health care provider, and is available by prescription only (Fig. 2).

In March 2002, the US FDA approved a new female barrier contraceptive, Lea's Shield[®] by prescription only (Fig. 3). The shield has been available over the counter since 1993 in Germany, Austria, Switzerland, and Canada. The second-generation FemCap[™], currently available in Germany, France, the United Kingdom, Austria, Switzerland, and the Netherlands, was approved for marketing by the US FDA in March 2003 (Fig. 4). Lea's Shield is "one size fits all" and



Fig. 4. Second-generation FemCap with removal strap. (Reproduced with permission from FemCap, Inc. and Alfred Shihata, MD.)

the size selection of the second-generation FemCap is determined by obstetrical history. Both Lea's Shield and FemCap are used with a spermicide and are available by prescription only.

Mechanism of Action

The cervical barrier methods prevent pregnancy by acting as a physical, and in some cases, chemical barrier to sperm movement.

The internal sheath of the female condom prevents sperm from entering the cervix and protects the vagina and cervix from STI exposure. The external ring also physically protects a large part of the perineum from STI exposure. The cervical cap, shield, contraceptive sponge, and diaphragm physically occlude the cervical os and hold a spermicide against it for added protection.

Lea's Shield is not held in place by the cervix, but rather by the vaginal wall, therefore cervical size does not play a role. Once inserted, the air trapped between the cervix and the shield escapes through the one-way valve, creating a tight fit between the vaginal wall and the shield (Fig. 5). The bowl of Lea's Shield is large enough to accommodate any normal-sized cervix. The second-generation FemCap is also held in place by the muscular walls of the vagina so it does not need to fit snugly around the cervix or hinge behind the pubic bone. The portion of the cap facing away from the cervix is shaped like an inverted funnel that directs sperm into the groove where the spermicide is stored.

The diaphragm is anchored in place between the pubic bone and the posterior fornix. This distance varies from woman to woman, and thus the diaphragm must be fitted and correctly sized. A spermicide is placed inside the dome before insertion.

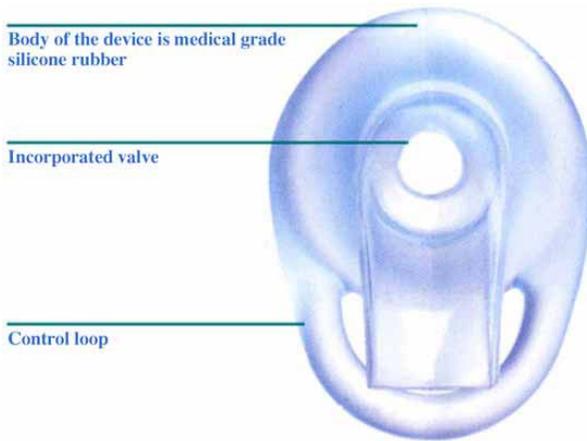


Fig. 5. Lea's Shield. (Reproduced with permission from Yama, Inc.)

The sponge is made from polyurethane foam that absorbs semen before the sperm have a chance to enter the cervix. It also contains a spermicide.

Effectiveness of Cervical Barrier Methods

As with all barrier methods, cervical barrier methods are most effective if used from “beginning to end” on every sexual contact. It is estimated that at least half of the pregnancies occurring in women who claim they were using a cervical barrier contraceptive are the result of improper or inconsistent use of the method. Both perfect use and typical use failure rates for cervical barriers are also affected by other factors including intercourse frequency and user fecundity. Some of the older cervical caps had much higher failure rates in parous compared with nulliparous women (32). However, newer-generation products are designed to grossly cover the cervix and upper vagina (rather than fit tightly around the cervix) and newer reports show very little differences in failure rates between parous and nulliparous women.

Because of the large number of variables that can affect failure rates of barrier methods, large differences in failure rates are reported in the literature. To reflect some of this variability, the effectiveness rates noted below are given as ranges.

EFFECTIVENESS OF THE DIAPHRAGM

Data from several studies (33–35) demonstrates a modest increase in effectiveness when comparing diaphragm use with and without a spermicide.

- For perfect use of the diaphragm, 2–8% of users will have an accidental pregnancy during the first year.
- In “normal” populations in which use is not always consistent or proper, the typical use failure rate is between 6 and 28% diaphragm users (36,37).

EFFECTIVENESS OF THE FEMALE CONDOM

- If used correctly on each act of sexual intercourse (perfect use), about 5% of female condom users will experience an unintended pregnancy during the first year of use.
- In “normal” populations in which use is not always consistent or proper, the typical use failure rates are 12–22% for female condom.

EFFECTIVENESS OF THE CERVICAL CAP AND SHIELD

- For perfect use, cap failure rates (primarily based on older and no-longer-available models) are 8–15% in nulliparous users and 20–30% in parous women (38).
B Failure rate for Lea’s Shield is around 9–14%; 6-month failure rate of 6.4 per 100 women with a spermicide and 12.2 per 100 women when used without.
 - FemCap (first-generation, now obsolete) was 86.5% successful in preventing pregnancy in the 6-month clinical trials. The increased dimensions of the brim are designed to increase the stability and effectiveness of the second-generation FemCap.
 - ♦ Based on the small studies to date of the second-generation FemCap, the typical failure rate is estimated to be 7.6%. For perfect use, it is estimated that the failure rate is 2–4%. Perfect use includes using FemCap correctly every time, applying spermicides with each act of intercourse, and using emergency contraception as back-up if the cap is used incorrectly (39).

EFFECTIVENESS OF THE VAGINAL SPONGE

In older studies, when the vaginal sponge was used correctly, about 9–14% of nulliparous and 9–27% of parous women became pregnant. Typical failure rates in nulliparous sponge users range from 9 to 21% and from 10 to 40% in parous users.

- Some newer studies of the Today[®] Sponge report lower failure rates in all women, regardless of their previous child-bearing history (91% effective in nulliparous women and 89.9% effective for parous women [40–42]).

Advantages of Cervical Barrier Methods

The cervical barrier methods have many advantages and are particularly good for motivated women who need intermittent protection. There are no systemic side effects and they can be backed up with emergency contraception to improve efficacy rates. Generally, these methods do not require more than limited partner involvement and are relatively easy and inexpensive to buy. Depending on the method, there are variable degrees of protection from STIs.

ADVANTAGES OF THE DIAPHRAGM

- Allows better sexual spontaneity and more sexual sensation than male condom use (43).
- Easy to use, reversible, affordable.



Fig. 6. Female condom showing outer ring with inner sheath and inner ring.

- Female-controlled contraception.
- The diaphragm is a barrier that may offer limited protection of the cervix from STIs (44,45).
 - B Observation trials have had variable results regarding protection from chlamydia, gonorrhea, and trichomoniasis (46).
 - B Several observation trials have reported that the diaphragm users have a lower risk of cervical dysplasia and cancer (47–49).

ADVANTAGES OF THE FEMALE CONDOM

- The polyurethane material making up the sheath of the female condom is impenetrable to HIV virus and to other STIs (50). The inner and outer ring of the female condom prevents contact between the penis and the vagina and perineum (Fig. 6).
 - B The female condom may offer as much protection (51) as the male condom, although more studies are needed.
 - B Failure of protection occurs if the condom is torn or if the penis is not placed correctly inside the condom.
- The female condom can be placed in the vagina up to 8 hours before intercourse.
- The polyurethane material in the female condom is stronger than a male condom and less likely to tear or break.
 - B It can be stored for long periods of time.
 - B It does not deteriorate when exposed to an oil-based lubricant.

ADVANTAGES OF THE SECOND-GENERATION FEMCAP AND LEA'S SHIELD

- The current labeling gives cervical caps the longest duration of use of all the cervical barrier methods, that is, up to 48 hours of protection.
- No effects on sexual desire or pleasure.
- Can be inserted up to 42 hours before sexual intimacy.
- Safe and highly acceptable to many women and men.
- Easy to learn and simple to use (patient instructional brochure and video tape provided).
- Minimum training time for a health care provider.
- Fitting not necessary and usable by most women.

B FemCap comes in three sizes and obstetrical history determines the size.

B Lea's Shield is a one-size-fits-all product.

- Inexpensive and reusable for 1 year.
- No effect on fertility, instantly reversible when pregnancy is desired.
- No effects with breastfeeding or breast milk.
- Woman can have full control (no male involvement necessary).
- Portable with discrete cover.
- May offer similar protection from STIs as the diaphragm, although further studies needed. Protecting the cervix (covering the cervix plus use of an appropriate microcide) may be an important factor in preventing disease transmission (52).

B FemCap provides a microbicide reservoir on the vaginal side that provides immediate contact of any STI/HIV virus with the microbicide (53).

- Made of durable, latex-free material that is easy to clean.
- Although acceptability ratings have varied, in some studies 87% of women said that they would recommend Lea's Shield and 55% of male partners said they liked the device. Of women who express an opinion regarding the diaphragm, 84% reported they preferred Lea's Shield (54).

ADVANTAGES OF THE SPONGE

- Contraceptive protection lasts for up to 24 hours no matter how many sexual contacts occur.
- One size fits all.
- Easy to use, inexpensive, portable.
- Over-the-counter availability.
- May provide limited protection from some STIs (gonorrhea, chlamydia) (55).

Disadvantages

The most common disadvantages to cervical barrier methods are related to local irritation or physical discomfort. When used with a spermicide, the nonoxyl-9 can be very irritating, especially if used frequently. Increases in vaginal discharge, urinary tract infections, bacterial vaginosis, and candidiasis are problems related to use. A certain amount of preplanning and interruption of sexual activity

may be necessary. Importantly, cervical barrier methods are not as effective as many other methods of contraception including oral contraceptive pills, intrauterine devices, implants, and injectables.

DISADVANTAGES OF THE DIAPHRAGM

- The diaphragm must be fitted by a trained health care worker.
 - B Refitting may be necessary following childbirth, significant weight gain (usually >10–15 lb), vaginal or pelvic surgery, or if the current size is associated with bothersome vaginal irritation.
 - B Women with poor vaginal tone, cystocele, rectocele, or uterine prolapse may not be able to use a diaphragm.
- Wearing a diaphragm for more than 24 hours may increase the risk for toxic shock syndrome (2.4 cases per 100,000 women using diaphragms [56]).
- Urinary tract infection more common in users (57,58).
- Although not common, rectal, bladder, or uterine discomfort may occur.
 - B Dyspareunia is rarely reported.
- Vaginal abrasion or laceration may occur, but is not common.
- Latex allergies are rare but are more common in health care workers who may have repeated exposure to latex gloves over many years.
 - B Those with hypersensitivity to latex may use wide-seal rim diaphragm.
- Side effects of spermicides include irritation to either partner especially with frequent use, allergy to nonoxyl-9, and concerns over potential teratogenic effects if a fetus is incidentally exposed, although studies report no relationship (59).

DISADVANTAGES OF THE FEMALE CONDOM

- The female condom may be physically uncomfortable to either the female user or male partner.
 - B Occasionally, it may irritate the vagina or penis.
- Some couples complain that it decreases sensation.
- Some may find the appearance of the female condom unappealing or awkward, especially at first.
- A certain amount of “buy-in” from the male partner may be necessary.

DISADVANTAGES OF CERVICAL CAP AND SHIELD

- Needs a prescription.
- Newer caps fit most nulliparous and parous women, although those with significant uterine or vaginal prolapse may not be good candidates.
- A few weeks needed to learn how to use the device properly; a back-up method is recommended during this time.
- Women may need to squat down to insert.
- The cap and shield provides up to 48 hours of contraceptive protection after placement, but this length of use may be associated with odor and discharge.
 - B Longer use may increase the risk of toxic shock syndrome.

- Women may forget and leave the cap in longer than 48 hours because they are unable to feel its presence. Women may find that monitoring insertion and removal with a calendar may avoid this problem.
- Vaginal dryness, vaginal abrasion or laceration, dyspareunia, penile irritation, bladder pain, or cramps may occur.
- Side effects of spermicides as listed in “Disadvantages of the Diaphragm” section.
- Planning necessary before sexual intimacy; must be placed before sexual arousal to avoid interruption of spontaneity and misplacement of the cap.
- Rarely, the male partner may have a sense of awareness and may object to its use.

DISADVANTAGES OF VAGINAL SPONGES

- Sponge must be placed just before intercourse and may interrupt sexual intimacy.
B The sponge must be moistened with water before insertion.
- Sponge removal may be problem, especially in new users.
- The sponge must be left in place for at least 6 hours after intercourse.
- Foul odor or vaginal discharge common if the sponge left in place for more than 24 hours.
- Conflicting data suggests the sponge may be less effective in parous women (new studies report the sponge has similar effectiveness in parous and nulliparous).
- Side effects of spermicides as listed in “Disadvantages of the Diaphragm” section.

Good Candidates for Cervical Barrier Methods

- Motivated women who need intermittent protection.
- Women who cannot or prefer not to take hormonal contraceptives.
B Women over 35 who smoke or have known cardiovascular disease or clotting problems or those with significant risk factors for cardiovascular disease.
- Women who need a back-up method, such as when pills are missed, during first month of pill use, or while using drugs that interfere with pill effectiveness.

CANDIDATES FOR THE DIAPHRAGM, CERVICAL CAP, AND SHIELD:

ADDITIONAL CONSIDERATIONS

Women with an allergy to latex are candidates for the cervical barriers made with silicone including the wide-seal rim diaphragm, cervical cap, and shield. Women with a history of frequent urinary tract infections or those that develop frequent urinary tract infections when using a diaphragm may find the cervical cap or shield a good option.

The diaphragm, cap, and shield are generally not recommended for women with the following:

- Significant vaginal abnormalities that interfere with placement.
B Severe uterine prolapse, vaginal septum.
- During first 4–6 weeks after childbirth because of lochia or during heavy bleeding.
- Allergy or sensitivity to spermicides.
- History of toxic shock syndrome.

- Unstable, unpredictable, spontaneous sexual habits.
- Women uncomfortable with genital manipulation or inserting and removing foreign devices from their vaginas.

Additionally, the cervical cap is not recommended for women with:

- Current cervicitis or vaginal infection.
- Current pelvic, tubal, or ovarian infection.
- Polyurethane allergy.
- Abnormal/unresolved pap smear.

CANDIDATES FOR THE FEMALE CONDOM: ADDITIONAL CONSIDERATIONS

- Women with significant uterine or vaginal prolapse may be limited to the female or male condom.
- Women at risk for STIs or HIV transmission are good candidates for condom use (not as much data to support protection with female condoms as there is for the male condom).

CANDIDATES FOR THE VAGINAL SPONGE: ADDITIONAL CONSIDERATIONS

Any woman who is comfortable using tampons or other vaginal contraceptives is a candidate for the sponge. Women should not use the sponge if:

- Either a woman or her partner have a sensitivity to:
 - B Sulfa drugs. A very small number may be allergic to the metabisulfite preservative in the sponge.
 - B Spermicide (Nonoxynol-9).
 - B Polyurethane.
- She has a significant vaginal abnormality.
- She cannot risk any chance of pregnancy whatsoever.
- She has a risk of exposure to STIs or HIV (sponge may be used with a condom).
- She has had toxic shock syndrome.
- Within 4–8 weeks of a vaginal delivery.
- During menstruation.
- During a current vaginal infection.

Patient Counseling

The most common problems related to cervical barrier methods are local irritation, foul odor, or discharge. These usually abate within a few days after removing the method. When trying to select the best cervical barrier for a motivated user, consider the timing and style of protection she needs. Vaginal spermicides give 1 hour of protection, the diaphragm provides 6 hours of protection, the sponge provides 24 hours, and the cervical cap provides 48 hours of protection after insertion. The female condom is the method of choice in women with risk of STI exposure but may be more cumbersome and requires some partner cooperation. The diaphragm, cap, and shield must be cleaned and stored,

Table 2
 Danger Signs of Toxic Shock Syndrome

Especially concerning if a barrier method has been in place for a prolonged period of time (longer than 24–30 hours).
High fever
Sore throat
Rash
Diarrhea or vomiting
Dizziness, fainting
Weakness, muscle aches

are used with a spermicide, and require a prescription. The diaphragm must be fitted by a health care provider. The female condom and sponge are readily available over the counter. Those who often use oil-based lubricants or medications are not good candidates for a latex diaphragm (Table 1).

A serious, although rare, side effect of cervical barriers is toxic shock syndrome. The danger signs are listed in Table 2. A comparison of barrier methods is given in Table 3.

DIAPHRAGM: INSTRUCTIONS FOR USE

Instructions on how to use a diaphragm are included with the diaphragm. Some women find squatting the easiest position, whereas others find lying down or standing with one foot on a chair the best position.

Inserting a Diaphragm Without An Inserter: An Arcing-Spring (All-Flex) or Coil-Spring Diaphragm (Fig. 7)

- After a contraceptive cream or jelly is placed in the center of the cup (some recommend that it be placed on both sides of the diaphragm) the diaphragm is folded together so that the cream or jelly is held inside. Some women find placing some on the rim makes insertion easier. The folded diaphragm is gently inserted into the vagina with the edges facing forward/upward. The diaphragm is then pushed as high as comfortably possible so that the lower rim rests behind the public bone and the higher rim slides up behind the cervix into the fornix. With proper placement, the dome of the diaphragm should completely cover the cervix, placing the spermicide directly against the cervix.
 - B The patient should be taught how to locate the cervix behind the dome of the diaphragm to insure proper placement. The cervix feels like a “nose” that should be covered completely by the diaphragm.
- If placed properly, the diaphragm provides 6 hours of protection. It must be kept in place for 6 hours after intercourse but no longer than 24 hours. For repeated acts of intercourse within the first 6 hours, the diaphragm should not be removed, but additional spermicide should be placed vaginally.

Table 3
Barrier Methods Time Comparisons

<i>Method</i>	<i>May insert before intercourse</i>	<i>Protection after insertion lasts for</i>	<i>After last intercourse, leave in place for at least</i>	<i>Remove within</i>
Diaphragm	30 minutes to less than 6 hours prior	6 hours (Additional spermicide added for each additional intercourse.)	6 hours	24 hours
FemCap™ (second generation)	Should be inserted 15 minutes (up to 42 hours) before the start of sexual activity	48 hours (Check the position of FemCap and insert additional spermicide without removing the cap before each repeated intercourse within the next 48 hours.)	6 hours	48 hours
Lea's Shield®	Should be inserted before the start of sexual activity	48 hours (Additional spermicide needed if intercourse occurs after 8 hours.)	8 hours	24 hours
Sponge	Up to 90 minutes prior	24 hours	6 hours	24 hours
Female condom	0–8 hours prior	While in place	Immediate removal after intercourse	
Male condom	After erection	While in place	Removal while penis still erect	
Vaginal spermicides	5–60 minutes depending on type	1 hour	6 hours	

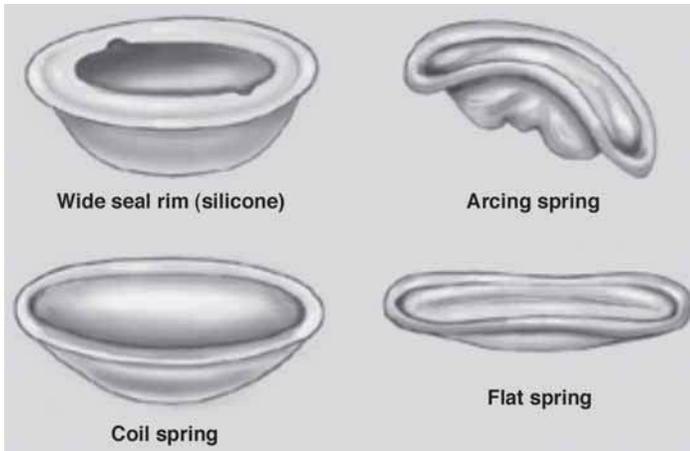


Fig. 7. Types of diaphragm rims. (Reproduced with permission from Marie Dauenheimer, MA, CML.)

- To remove the diaphragm, the front rim is either grasped using two fingers or hooked using one finger. For removal it is sometimes necessary to pull the diaphragm away from the underlying vaginal tissue because a slight suction may hold the diaphragm in place.
 - B The diaphragm should be cleaned with mild soap and air-dried.
 - B Check the diaphragm for holes or tears by visual inspection and by holding it up to the light.

Inserting a Diaphragm With An Inserter: Flat- or Coil-Spring Diaphragm (Fig. 7)

- This diaphragm comes with a special plastic applicator that has a series of small notches, corresponding to the size in centimeters of a diaphragm. The diaphragm rim, with the dome facing upward, is hooked into the large notch at the end of the applicator. The other end of the rim is hooked into the notch corresponding to the size of the diaphragm. By doing this, the diaphragm is stretched into a flat oval with the dome puckered into folds. The spermicide is placed into these folds and a small amount placed around the rim. With the spermicide facing upward, the applicator is placed into the vagina and angled toward the small of the back. It is slid into the small space between the cervix and the rear wall. When pushed as far as it will go, the applicator is twisted to release the diaphragm and then removed. With one finger, the front edge is pushed up behind the pubic bone. Finally, a check is made to make sure that the diaphragm covers the cervix.

INSTRUCTIONS FOR USE: FEMALE CONDOM

- The female condom is available as an over-the-counter product and is marketed for one-time use.
- The female condom can be inserted up to 8 hours before intercourse.

- It should not be used with a male condom because the two condoms may stick to each other and cause discomfort or displacement.

Instructions for insertion:

- For insertion, the inner, smaller ring is squeezed and inserted into the vagina. The outer rim is placed evenly over the introitus.

INSTRUCTIONS FOR USE: CERVICAL CAPS

To ensure correct placement, the FDA has strongly advised women to insert the FemCap before sexual arousal. FDA also recommends that a back-up method be used during the learning phase and that emergency contraception be used as a back-up method, if needed, in case the woman has not used the FemCap or has used it incorrectly. There is an instructional video supplied with the FemCap.

After removing a cap, wash the device with a mild soap, air-dry, and store it in its original container in a cool, dry place. Before using the device again, inspect it for weak spots or pinholes by holding it up to a light or by filling it with water.

All prescription barrier devices eventually wear out. Diaphragms and cervical caps often need to be replaced after 1–2 years of use, and a cervical shield may last 6 months to 2 years. A new fitting for a diaphragm may be necessary after a pregnancy, significant weight gain or loss, or abdominal or pelvic surgery. A change in FemCap size may be necessary after a pregnancy, including miscarriage, induced abortion, or delivery.

Insertion/Removal of FemCap

The FemCap has an asymmetrical rim designed so that the larger rim fits into the top of the vagina. Spermicide is placed on the inner and outer surfaces. It may be necessary to tip the rim of the cap to release the suction for removal.

- Knowing the position of the cervix is very important because the cervix is the target, and knowing where it is helps to determine how deep to place the FemCap. To check the position of the cervix, it may be easiest to squat down and bear down and insert a finger deep into the vagina. The cervix feels like the tip of a nose.
- Apply a very small amount of spermicide (about 1/4 tsp.) in the bowl of the FemCap and spread a thin layer over the outer brim (but not over the area where the cap is being held). Turn the cap over and apply the bulk of spermicide (about 1/2 tsp.) in the groove between the brim and the dome. (This is the area that faces outward from the cervix and collects most of the sperm when placed correctly (Fig. 8).
- The squeezed, flattened cap is inserted into the vagina with the bowl facing upward and the long brim entering first.
- FemCap is pushed downward toward the rectum and slid as high into the vagina as possible.
- After placement, a finger should be used to make sure the cap is pushed all the way in and covers the cervix completely. Make sure that it is not partway between the vaginal opening and the cervix.

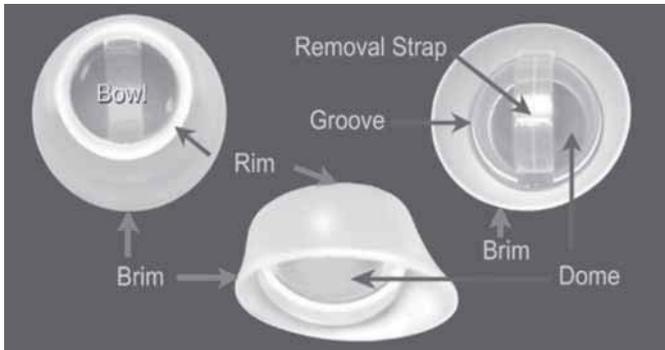


Fig. 8. The bowl of the second-generation FemCap is placed over the cervix. It is designed to cover the cervix completely. The brim forms a seal against the vaginal wall and funnels the ejaculate fluid into the groove. (Reproduced with permission from FemCap, Inc. and Alfred Shihata, MD.)

- B If the FemCap is placed correctly, women are rarely aware of its presence during either daily activities or during intercourse. Men also are usually unaware of its presence and it should not interfere with sexual pleasure.
- Wait at least 6 hours after the last act of intercourse before removing the cap. To remove the cap, it is best to squat and bear down. This will bring the cap closer to the vaginal opening.
 - B Rotate the FemCap in any direction, or push the tip of a finger against the dome to dimple it. These maneuvers help to break the suction and allow a finger to fit between the dome and the removal strap. Hook the removal strap with the tip of a finger and gently pull it down and out of the vagina.
 - B Wash the FemCap with soap and rinse it with tap water. Pat dry and allow the cap to air-dry.
 - B Store the cap in its plastic storage container.

Insertion of Lea's Shield

Lea's Shield is much like a diaphragm, although it is designed to fit around the cervix. It has a central one-way valve that allows for cervical mucus to pass. It is one size fits all so that fitting in not required. It is not necessary to form suction with the cervix when using Lea's Shield.

Insertion of Lea's Shield is almost as easy as insertion of a tampon. Studies showed that the average woman can learn how to insert and remove the Lea's Shield just by reading the Lea's Shield user manual. Lea's Shield consists of a cap-shaped appendage and a "control loop" that together form an elliptical device. The shield is placed behind the pubic bone, as far as it can comfortably go. The loop aids in insertion and removal of the shield and stabilizes the device. When in place, the lower tip of the cap is positioned under the cervix (with the cervix

resting in the interior of the cap) while the control loop extends toward the posterior aspect of the pubic symphysis.

- Spermicide should be applied to the rim and the bowl (one-third full) of the device before insertion.
- Squeeze the device.
- Insert it and push it in as far as it can go. It “settles in place” and automatically completely covers the cervix.
- Additional spermicide is only required if sex occurs more than 8 hours after insertion. If more spermicide is required, it should be placed in the vagina without removing Lea’s Shield.
- For removal, grasp the loop with one finger and remove the device.
- Lea’s Shield should be washed thoroughly with mild liquid soap for approximately 2 minutes, dried, and then stored in its silk pouch (*see* user manual).
- It is recommended that Lea’s Shield be replaced if it shows any signs of wear or deterioration.

Insertion of Prentif™ Cavity Rim (Currently Unavailable Because of Manufacturing Difficulties)

Before use, a spermicide is placed in the cervical cap, filling it to about one-third full. The cap is placed against the cervix with the lower rim fit snugly placed under the cervix. As the cap is placed, it is unfolded. As the dome expands, suction is produced that holds the cap in place. It may be necessary to tip the rim of the cap to release the suction for removal.

INSTRUCTIONS FOR USE: VAGINAL SPONGE

- Remove the sponge from its pouch. Moisten it with about 2 tbsp. tap water and gently squeeze to activate the spermicide.
- Fold the foamy sponge in half with the dimple side facing upward. Holding the sponge between two fingers, insert it deep into the vagina, up to and against the cervix. The dimple should face the cervix and the loop should face away from the cervix. Palpate around the sponge to make sure it completely covers the cervix.
- After intercourse, wait at least 6 hours before removal.
 - B For removal, place a finger into the vagina and reach upward to find the loop.
 - B Bear down and push the sponge toward the vaginal opening. Hook the finger around the loop or grasp the sponge between fingers.
 - B Withdraw the sponge from the vagina. If the vaginal muscles are tight and removal is difficult, relax, wait a few minutes, and try again.

Selecting Available Options, Fitting, and Counseling

SELECTING THE CORRECT DIAPHRAGM

There are four major types of diaphragms as determined by the rim flexibility, degree of arch, spring strength, and width (Fig. 7). The arching-spring diaphragm

is the easiest type to insert because it has a firm rim that forms an arch when folded. The arching spring is a good choice for women with decreased vaginal tone or pelvic relaxation. Latex diaphragms are available in all rim styles and silicone diaphragms are available as wide-seal rims in either the arching or coil spring type. Diaphragms fitting rings come in sizes 60–90, although actual diaphragms are available from size 50–105 mm in diameter. The all-flex diaphragm is very popular and allows a moderate, even, and usually comfortable spring strength. The most common size diaphragm is 75 mm.

Diaphragm manufacturers supply a set of fitting diaphragms or fitting rings that come with a variety of rim spring strengths. It is generally best for the patient to practice insertion and removal with the fitting diaphragm and be given a prescription for the same size and same rim style.

- Coil-spring diaphragm (coiled wire).
 - B Soft, flat, flexible rim with intermediate spring strength.
 - B Intended for women with average vaginal tone (average strength of the vaginal muscles) and no genital abnormalities. Good for those who feel the arching-spring diaphragm to be too firm.
 - B Folds flat when folded for insertion and can be inserted with an introducer.
 - B Products: Koromex[®], sizes 50–95, latex; Ortho[®], sizes 50–100, latex; Ramses[®] Flexible Cushioned, sizes 50–95, gum rubber.
- Arching-spring diaphragm (combination metal spring).
 - B Very firm, sturdy rim with firm spring strength.
 - B Can be used by all women; also intended for women with weak vaginal tone, moderate descent of bladder or rectum (cystocele or rectocele), or with their uterus bent far forward or backward, average pubic notch.
 - B Very popular because it offers the easiest insertion because it bends everywhere and forms an arch when folded.
 - B May be less comfortable than the other two styles after insertion.
 - B Products: Koroflex[®], sizes 60–95, latex; Allflex[®], sizes 55–95, latex; Ramses Bendex, sizes 65–95, gum rubber.
- Wide-seal rim.
 - B Has a flexible, 1.5-cm wide flange attached to the inner edge of the rim. The flange holds the spermicide inside the diaphragm and forms a tight seal between the vaginal wall and the diaphragm, providing increased suction action, which minimizes risk of diaphragm dislodging during intercourse.
 - Available with either an arcing or coil spring (Omniflex).
 - B Distributed directly to clinic or directly from the manufacturer.
 - B Products available:
 - Milex[®] Wide-Seal Arching, sizes 60–95, latex; Milex Omniflex Coil Spring, sizes 60–95, latex.
 - Milex Wide-Seal Silicone Arching and Omniflex.

- Silicone associated with longer shelf life, does not absorb odors or secretions, can be autoclaved, hypoallergenic.
- Flat-spring diaphragm (flat metal band).
 - B Thin, flat, delicate rim with gentle spring strength (similar to coil spring but thinner).
 - B Intended for women with very firm vaginal tone, nulliparous, a shallow pubic arch, or those with a shallow notch behind the pubic bone.
 - B May not be stocked in all pharmacies.
 - B Folds flat for insertion and can be inserted with a diaphragm introducer.
 - B Products: Ortho-White® Diaphragm, sizes 55–95, latex.

Women who are not satisfied with a particular style diaphragm may find that another style is significantly more acceptable. In a study in college students, overall satisfaction throughout 1 year of use was significantly better with the coil-spring diaphragm compared with the arching-spring diaphragm. The study results demonstrate that certain diaphragm styles may improve women's use of and satisfaction with the diaphragm (60).

DIAPHRAGM FITTING AND COUNSELING

Proper fitting and patient education along with user motivation are the keys to success (61). (See Table 3.)

An extended visit may be needed for proper fitting and counseling. Diaphragm-fitting rings can be obtained from the manufacturer. Examination gloves and vaginal lubricating gel are used during the fitting. Optimally, the patient should do at least one insertion and removal while still in the clinic in case she experiences problems. Practicing again at home before use is advisable.

- A middle and index finger (or measuring instrument) are used to measure the distance from the bottom of the pubic bone to the posterior fornix of the vagina. Before the fingers are removed, the thumb (or an instrument) is used to mark the spot where the public arch touches the top of the index finger. This measurement is then used to select a diaphragm size (75 mm is a common size).
- The selected size is lubricated, folded in half, and then placed in the vagina with the two rims touching and facing upwards. Holding the vulva open with one hand, the health care provider uses the other hand to insert the folded diaphragm into the vagina and to direct it into the posterior fornix. The correct placement of the diaphragm is then confirmed by palpating the cervix through the dome of the fitting diaphragm. The anterior rim is then checked to see that it fits snugly and directly behind the pubic bone.
 - B The size that best fits is the one that completely covers the cervix and extends into the posterior vaginal fornix while fitting securely/gently behind the pubic symphysis. Generally, the proper fit is the largest diaphragm that is comfortable for the client.

- Checking that the proper size has been selected by checking the fit of one size larger or one size smaller may be helpful.
 - ♦ A too-small diaphragm will not fit up snugly behind the pubic bone and it will fall out when the patient sits on the toilet, ambulates, or does a Valsalva's maneuver.
 - ♦ A too-large diaphragm will rest improperly in front of the public bone and be uncomfortable; it may interfere with urination.
- The diaphragm is removed by “hooking” the anterior rim with a finger and pulling the diaphragm down and out of the vagina.
- After the correct size is determined, the patient should be taught:
 - B How to place about 1 tsp. of the spermicide into the dome of a diaphragm (for added efficacy, jelly can be applied around the rim).
 - B How to insert the folded diaphragm.
 - B How to feel for the cervix through the dome.
 - B How to remove the diaphragm.
 - B Instructions: the diaphragm must remain in place for at least 6 hours after intercourse but not for more than 24 hours.
 - For additional acts of intercourse, the diaphragm remains in place and additional spermicide jelly is inserted.
 - The diaphragm is washed and checked periodically for holes, but many last several years.

ONE AVAILABLE OPTION: FEMALE CONDOM

Reality[®], the only female condom on the US market today, was approved by the FDA in 1993. The female condom consists of two flexible polyurethane rings and a loose-fitting polyurethane sheath. One ring is at the base of the sheath and is used for insertion and for holding the top of the sheath in place at the top of the vagina. The other ring forms the external opening and holds the outer portion of the sheath over the perineum. The inner lining of the sheath is coated with a lubricant and an additional lubricant can be use on the exterior for easier insertion. The female condom contains no spermicide.

SELECTING THE PROPER CERVICAL CAP OR SHIELD

- Lea's Shield was approved by the FDA in 2002. Lea's Shield can be ordered from YAMA, Inc. (Millburn, NJ; <http://www.birthcontrol.com/leabody.html>). It is a one-size-fits-all oval cap containing a central valve that allows passage of cervical mucus or discharge. It has an attached loop that helps with removal. It is used with a spermicide and is similar in use to a diaphragm. It is made of medical-grade silicone rubber.
- The second-generation FemCap comes in three sizes as determined by the inner diameter of the rim (FemCap Inc., Del Mar, CA, www.femcap.com). The fit of the FemCap is determined by the obstetrical history of the potential user. Women who have never been pregnant will use the 22-mm FemCap; women who have

been pregnant but never delivered vaginally (miscarried or had caesarian section) will use the 26-mm FemCap; and women who have vaginally delivered a full-term baby will use the 30-mm FemCap. If in doubt, the medium size is recommended.

B The FemCap is made with silicone rubber and has an asymmetrical rim that flares outward. The cap fits over and completely covers the cervix and the rim fits into the vaginal fornices, the larger brim fitting into the back of the vagina. The FemCap has a brim, a dome, a groove between the dome and the brim, and a removal strap.

B The retail price is around \$50 for a single FemCap and it should last 2 years. The FemCap kit contains an FDA-approved instructional videotape. It is recommended that a back-up method be used during the first few weeks of use.

- The Prentif Cavity Rim cervical cap is a deep cap made of rubber that has a solid round rim. It is designed to fit firmly around the cervix. A small groove, located along the inner rim is designed to improve the seal between the cap and the cervix. A spermicide is placed to partially fill the cap before insertion. The Prentif Cavity-Rim cervical cap was previously available in sizes 22, 25, 28, and 31 mm. Because of manufacturing difficulties and low sales, this cervical cap is no longer available in the United States.

ONE AVAILABLE OPTION: VAGINAL SPONGE

Today sponge has been recently reintroduced into the US over-the-counter market (Allendale Pharmaceuticals). The availability of the sponge may be currently limited. The sponge is a one-size-fits-all, small, round polyurethane sponge containing nonoxynol-9 spermicide. The concavity on one side is designed to fit over the cervix. On the other side is a loop that helps with removal of the sponge after use.

In Europe, there is a tablet called Pharmatex that uses the spermicide benzaikonium chloride. Another sponge, called Protectaid® is manufactured in Canada. It is designed to cause less vaginal irritation by incorporating three different spermicides in low concentrations.

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