

## Barrier Methods

**B**arrier methods of contraception use a mechanical or chemical barrier to prevent sperm from passing through the woman's cervix into the uterus and fallopian tubes to fertilize an egg. Some barrier methods also protect against STIs. Many barrier methods such as male and female condoms, spermicides, sponges, certain cervical caps (FemCap), and diaphragms (Caya diaphragm) can be obtained without a prescription and do not require consultation with a health care provider before use. The silicone diaphragm (Milex wide-seal) requires an initial visit to a health care provider for fitting. For maximum effect, barrier contraceptive methods must be used correctly and consistently.

### MALE CONDOMS

A male condom is a sheath that covers the penis during intercourse and acts as a physical barrier to prevent sperm from entering the vagina. Male condoms may be made of latex, polyurethane, polyisoprene, silicone, or lambskin. Condoms are a safe, effective, and inexpensive user-controlled method of contraception. In Canada, condoms are the most common method of contraception used by women of reproductive age.<sup>1</sup>

Latex condoms, <sup>2-4</sup> although they are less effective in preventing STIs that are transmitted by skin-to-skin contact, such as herpes and HPV, than those that are transmitted by body fluids because they do not cover all of the infected skin area. The level of protection against each specific STI has not been quantified.<sup>5</sup> Latex condoms are offered in a variety of shapes, sizes, textures, and colours. Novelty condoms, such as those offered in sex toy supply stores or catalogues, cannot be sold for the prevention of STIs or pregnancy and they should not be used concurrently with a latex condom because they are made of materials that may weaken the latex.<sup>6</sup>

Latex condoms may have disadvantages such as decreased sensitivity during intercourse, difficulties putting on and removing, potential deterioration during storage or when exposed to oil-based lubricants,<sup>7,8</sup> and risk of latex allergy. Non-latex condoms (polyisoprene, polyurethane, silicone, and lambskin) were developed as alternatives for people

who had latex allergies, sensitivities, or preferences that prevented the consistent use of latex condoms.<sup>9</sup> Non-latex condoms usually cost more than latex condoms. Polyurethane condoms transmit more body heat, which allows more sensitivity and a thinner feeling with a less constricting fit. They are more resistant to deterioration and can be used with oil-based lubricants. Lambskin ("natural membrane") condoms prevent pregnancy but are not recommended for STI prevention.<sup>10</sup> Laboratory tests have shown that viruses such as hepatitis B, herpes simplex virus (HSV), and HIV can pass through small pores on the surface of lambskin condoms.<sup>11</sup>

In general, non-latex condoms do not perform as well as latex condoms due mainly to significantly higher odds of breakage or slippage.<sup>9</sup> This may increase concerns regarding their ability to prevent pregnancy and STIs; however, the effect on contraceptive efficacy and STI prevention has not been well studied.<sup>9</sup> Despite this, they may still be an acceptable alternative for those who cannot or are unwilling to use latex condoms.

### **Efficacy and Effectiveness**

Condoms are very effective when used consistently and correctly. The estimated probability of failure with perfect use is 2%, whereas typical-use failure rates are approximately 18%.<sup>12</sup> Randomized controlled trials have found significantly higher failure rates (breakage and slippage),<sup>13,14</sup> typical-use pregnancy probabilities,<sup>13</sup> and perfect use pregnancy probabilities<sup>14</sup> with polyurethane condoms than with latex condoms. A systematic review also found significantly higher odds of breakage with non-latex condoms than with latex condoms, but no difference in typical-use failure rates between the Avanti polyurethane condom, the Standard Tactylon, and latex condoms.<sup>9</sup> Polyisoprene condoms are made of synthetic latex, but do not have the allergenic component of natural rubber latex. There are no published data regarding their contraceptive effectiveness, but they are considered to be comparable to latex condoms due to similarity in manufacturing process and structural makeup.<sup>15</sup>

There is no evidence that condoms lubricated with N-9 are more effective in preventing pregnancy or sexually transmitted infections than lubricated condoms that do

not contain N-9. Due to the potential adverse effects of N-9, including an increased risk of HIV transmission,<sup>16</sup> the use of condoms lubricated with N-9 is not recommended.

### Mechanism of Action

The condom acts as a mechanical barrier to prevent exchange of fluid and semen. Some condoms tend to fit better than others; optimal fitting requires trying a variety of condoms.

### Indications

Condoms are indicated for the prevention of pregnancy and STIs. Ideally, condoms should be used in addition to another primary contraceptive method (dual protection), because condom use provides protection against STIs and additional backup contraception.

### Contraindications

The only relative contraindication to latex condom use is an allergy or sensitivity to latex.<sup>17,18</sup> Lanolin sensitivity is a contraindication to the use of lambskin condoms.

### Non-contraceptive Benefits

Condoms provide protection against STIs. A recent review of the effectiveness of condoms against the most common STIs emphasizes both the overall positive level of protection provided by condoms as well as the limitations in study design in trying to quantify this effect.<sup>3</sup> Latex condoms decrease the risk of transmission of STIs associated with cervical/vaginal discharge (chlamydia, gonorrhea, trichomoniasis).<sup>4,19,20</sup> A Cochrane Review found consistent condom use can decrease AIDS/HIV transmission by 80%.<sup>2</sup>

Regular and adequate use of condoms may also lower the risk of cervical neoplasia although there is no consistent evidence that it reduces the risk of HPV acquisition.<sup>21,22</sup> Condoms can prolong ejaculatory latency in men who have rapid/premature ejaculatory difficulties.

### Side Effects

Condoms may cause irritation. Spermicides used with condoms, including spermicide-coated condoms, increase the risk of *E. coli* urinary tract infections due to alterations in the normal vaginal flora.<sup>23–25</sup> Alterations in vaginal flora, vaginal irritation, and superficial abrasions may actually enhance the risk of HIV transmission<sup>26</sup> and hence spermicide-coated condoms are no longer recommended. Some men may complain of decreased sensation or loss of erection.<sup>27–31</sup>

### Risks

Technical problems with condom use (unrecognized leakage, slippage, breakage) are more common when men do not take enough time or care to properly apply the condom.<sup>28</sup> Common errors in condom use include not using condoms

throughout sex, applying the condom after penetration, removing it before ejaculation, not leaving space at the tip, not squeezing air from the tip, putting the condom on upside down, not using water-based lubricants (with latex and polyisoprene condoms), and incorrect withdrawal.<sup>31</sup> Frequent problems with condom use included breakage, slippage, leakage, condom-associated erection problems, and concerns with fit and feel.<sup>29,31</sup> Health care providers should be aware of these potential errors and problems when counselling patients on the use of condoms.

### Myths and Misconceptions

#### “Everybody knows how to use a condom.”

*Fact:* Errors in condom use are common.<sup>31</sup> Men and women require counselling on how to correctly and consistently use condoms in order to prevent condom “accidents” such as breakage or spillage.

#### “I can’t get an STI if I always use a condom.”

*Fact:* Condom use is a risk-reduction strategy. Consistent and correct use of latex condoms reduces the risk of transmission of many STIs and HIV but it does not provide absolute protection against any STI.<sup>4</sup> Latex condoms decrease the risk of transmission of STIs associated with cervical/vaginal discharge such as chlamydia, gonorrhea, and trichomoniasis, and decrease the risk of HIV transmission.<sup>4</sup> However, their protective effect against HPV is uncertain. Although one study showed a decrease in HSV-2 acquisition in consistent condom users whose partners were serodiscordant,<sup>32</sup> skin-to-skin contact with an active lesion may still result in STI transmission. Novelty condoms are not approved for STI prevention.<sup>6</sup>

### Initiation

Condoms are available for purchase in pharmacies and in many sexual health clinics. Innovative programs have been developed to improve access to condoms for individuals who find them difficult or embarrassing to purchase.<sup>33,34</sup> Condoms provided through school-based clinics or dispensing machines are innovative ways to improve uptake and use in young people.<sup>35–37</sup> Condoms are covered under Health Canada’s NIHB program of.<sup>38</sup>

### Proper Use and Precautions

Packaged condoms can be kept for up to 5 years if they are stored in a dry place away from light and heat. Condoms should not be used after their expiry date. Condoms deteriorate more quickly when exposed to temperatures over 37°C, high humidity, and air pollution.<sup>39</sup> Some condoms are pre-lubricated with silicone, jelly, or cream, which may help to prevent condom breakage during intercourse. Latex and polyisoprene condoms should only be used with water-based lubricants because oil-based

**Table 8. Lubricants and products that are safe or unsafe to use with latex condoms\***

Safe	Unsafe
<ul style="list-style-type: none"> <li>• Water and silicone-based lubricants (check package insert for confirmation)</li> <li>• Contraceptive foam and film</li> <li>• Glycerin USP</li> <li>• Egg white</li> <li>• Saliva</li> <li>• Water</li> <li>• Vaginal moisturizers</li> </ul>	<ul style="list-style-type: none"> <li>• Baby oil, mineral oil, suntan oil, fish oil, coconut oil/butter, palm oil</li> <li>• Olive oil, peanut oil, or vegetable oil</li> <li>• Margarine, butter</li> <li>• Hemorrhoid or burn ointments</li> <li>• Petroleum jelly (e.g., Vaseline)</li> <li>• Rubbing alcohol</li> <li>• Vaginal creams (e.g., Monistat, Estrace, Femstat, Vagisil, Premarin)</li> <li>• Some sexual lubricants (e.g., Elbow Grease, Hot Elbow Grease, Shaft)</li> </ul>

\*Check product insert and condom package for confirmation  
USP: United States Pharmacopeial grade

**Table 9. Using a condom**

- Put a drop or two of water-based lubricant or saliva inside the condom.
- Place the rolled condom over the tip of the erect penis.
- Leave a half-inch space at the tip to collect semen.
- If not circumcised, pull back the foreskin before rolling on the condom.
- Pinch the air out of the tip with one hand (friction against air bubbles causes most condom breaks).
- Unroll the condom over the penis with the other hand.
- Roll it all the way down to the base of the penis.
- Smooth out any air bubbles.
- After ejaculation and while the penis is still erect, hold onto the rim of the condom at the base of the penis so that the condom does not slip off.
- Do not spill the semen.
- Throw the condom away (do not flush down the toilet).
- Wash the penis with soap and water before any further contact.

lubricants can weaken condom integrity, reducing tensile strength, elongation, burst pressure, and burst volume (Table 8).<sup>7</sup> Condoms should not be disposed of in toilets.

Ideally, women and their partners should be educated on the correct use of condoms (Table 9), availability of emergency contraception, and STI screening. A new condom should be used with every act of intercourse. Condoms should not be reused. The condom must be put on after the penis is fully erect but before intimate contact.

In case of condom breakage or leakage, condom users should be aware of and consider emergency contraception as well as STI testing and PEP according to STI guidelines<sup>40</sup> if necessary.

### Troubleshooting

#### **“I don’t have the same feeling with a condom.”**

While condom use may reduce sensitivity, there is no objective evidence for this. Reduced sensitivity may be an advantage for some men by enhancing erection and preventing premature ejaculation. To increase sensation,

the male partner may use a textured, ultra-thin, or polyisoprene condom, place a water-soluble lubricant inside the reservoir of the condom, use the condom while masturbating, or ask his partner to roll it up over his penis.

#### **“I lose my erection when using a condom.”**

Making the application of the condom by the partner a part of sex play, for example during oral sex or masturbation, or learning to use the condom while masturbating may help overcome this obstacle.

#### **“Using a condom interferes with the spontaneity of sex.”**

Condom use may interfere with, or interrupt, foreplay and impair erection. Encouraging the partner to put the condom on as a part of sex play, eroticizing condom use, and using a condom during sex play before intercourse may alleviate this problem.

#### **“I am allergic to latex.”**

Couples who have a latex allergy or sensitivity can consider using polyurethane or polyisoprene condoms for both contraception and STI prevention.

**“The condom breaks or slips during intercourse.”**

Condom breakage may be due to rough handling, too much friction during intercourse, use of oil-based lubricants, incorrect storage (heat or light exposure), or usage after the expiry date. Condoms rarely slip off completely during intercourse, but they may slide down the shaft of the penis without falling off. The condom must be held at the base of the penis during withdrawal. Frequent slippage may indicate that the condom is too large and use of a more “snug” condom may be preferred. Emergency contraception should be used as soon as possible after a condom accident and STI testing/PEP should be considered according to the Canadian Guidelines on STIs.<sup>40</sup>

**“My partner does not want to use condoms during intercourse.”**

Health care providers can rehearse specific scenarios with their patients, walk through the process of when and how to purchase condoms, where to carry them, and when and how to bring up the subject of condom use. Negotiating skills to address resistance to condom use may be helpful.

**FEMALE CONDOMS**

The female condom is a soft, loose-fitting, seamless nitrile polymer sheath containing 2 flexible rings, one at each end. It is sometimes called an “internal condom.” The external ring at the open end of the condom sits outside the vagina and provides some perineal protection. The internal ring lies within the closed end of the pouch, allowing the condom to be inserted into the vagina and kept in place (Figure 3). The sheath is coated on the inside with a silicone-based lubricant. It can be placed in the vagina up to 8 hours before intercourse.<sup>41</sup> The female condom does not deteriorate with exposure to oil-based products and withstands storage better than latex.

The FC2 female condom is the only female condom available in Canada, replacing the FC1 polyurethane female condom (Reality). The female condom can be purchased in pharmacies without a prescription.

**Efficacy and Effectiveness**

The 12-month pregnancy rate for perfect (correct and consistent) use of the female condom is 5%, while the typical-use failure rate is 21%.<sup>12</sup> One randomized trial reported that the polyurethane female condom was as effective as a synthetic latex condom (5.24% vs. 4.3%).<sup>42</sup> Potential reasons for failure of the female condom include: breakage (during intercourse or when withdrawing the female condom from the vagina), slippage (the FC slips completely out of the vagina during sexual intercourse), misdirection (during vaginal penetration the penis is

**Figure 3. Female condom**

inserted between the female condom and the vaginal wall), and invagination (the external retention feature of the condom is partially/fully pushed into the vagina during sexual intercourse).<sup>43</sup>

**Mechanism of Action**

The female condom is an intravaginal barrier. It lines the vagina completely, preventing contact. The female condom is not intended for use with a male condom, because the 2 condoms may adhere to one another and slip or become displaced.

**Indications**

The female condom is the only method of dual protection (against both pregnancy and STIs) available specifically for women. A woman who does not like the other vaginal barrier methods may prefer to use the female condom.

The female condom has several advantages. A woman can place it autonomously. It does not require an erect penis for insertion. It is also safe to use for those with a latex sensitivity and can be used with oil-based lubricants. Male partners may find it more comfortable and less constricting than male condoms. The internal and external rings may make sex more enjoyable for the male or both partners by increasing stimulation.<sup>44</sup>

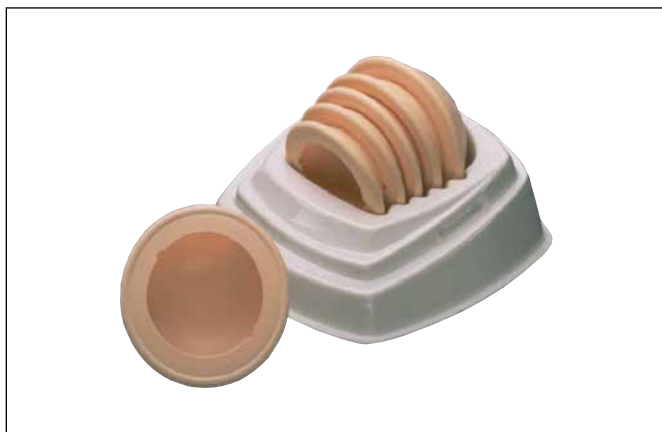
**Figure 4. Milex® Wide-Seal Silicone Omniflex Diaphragm**

Image provided by CooperSurgical, Inc.

### Contraindications

There is no absolute contraindication to the female condom.<sup>17</sup> Relative contraindications include an allergy to nitrile polymer, abnormal vaginal anatomy that may interfere with a satisfactory fit or stable placement, and inability to learn the correct insertion technique.

### Non-contraceptive Benefits

The FC1 was made of polyurethane, which is impenetrable in vitro to organisms the size of HIV.<sup>45</sup> There are no data available on efficacy and STI prevention for the synthetic nitrile polymer FC2, although it was approved on the basis that its properties were comparable to the polyurethane female condom.<sup>43</sup> There are no current data demonstrating that female condoms are equivalent to male condoms with respect to STI prevention.<sup>44</sup> One study noted more mechanical problems with the female polyurethane condom than the male condom<sup>46</sup> and thus semen exposure may be significantly higher with the FC compared to the male condom, particularly with the first few uses of the FC.<sup>46,47</sup>

### Side Effects, Risks, and Challenges

Slippage, breakage, misdirection, and invagination are possible challenges associated with use of the FC.<sup>43,44,48</sup> FC users must practise inserting the device to become confident. Although the rings may make sex more enjoyable by providing greater stimulation, they may also cause discomfort during coitus.<sup>49</sup> Typically, female condoms cost more than male condoms (approx. \$3 each in Canada) and are noisier during intercourse<sup>41</sup>; however, the new nitrile polymer FC2 may be less expensive and less noisy than the previous polyurethane versions.

### Initiation

Female condoms do not need to be fitted. For correct use the following instructions must be followed:

**Figure 5. Caya SILCS Diaphragm**

Produced with permission from the Trimed Supply Network Ltd.

- The FC must be inserted before penile penetration occurs. It can be inserted up to 8 hours prior to intercourse.
- Use a new FC for each act of intercourse.
- Remove immediately after intercourse by squeezing and twisting the outer ring before standing up to keep semen inside the pouch.
- Throw the FC away (do not flush).

### Troubleshooting

If the female condom slips or breaks, emergency contraception should be used as soon as possible if a pregnancy is not desired. Testing for STIs or obtaining PEP according to STI guidelines may also be appropriate.<sup>40</sup>

## DIAPHRAGM AND CERVICAL CAP

### Diaphragm

The diaphragm is an intravaginal barrier method of contraception that is used in conjunction with a gel. It fits into the vagina from the posterior vaginal fornix to behind the upper part of the pubic bone to cover the cervix.

There are currently 3 types of diaphragm available in Canada: the Milex Wide-Seal Silicone Omniflex Diaphragm (Figure 4), the Milex Arcing Diaphragm (not pictured; the arcing diaphragm is very similar in appearance to the wide-seal), and the Caya SILCS Diaphragm (Figure 5). The Omniflex diaphragm has a distortion-free spring that provides arc no matter where the rim is compressed and the arcing diaphragm has a tension-adjusted spring that curves in one place. The arcing diaphragm is recommended for women who have less pelvic support. The omniflex and arcing diaphragms

(size 65 to 95 mm) are available by prescription in pharmacies and must be fitted by a health care provider. Yearly replacement is recommended.

The SILCS diaphragm was approved by Health Canada in December 2013<sup>50</sup> and is made of silicone and nylon. It is available in one size and measures 67 mm in width and 75 mm in length. It fits most women (standard diaphragm size 65 to 80 mm for traditional diaphragm fitting). It has grip dimples at the side of the rim to provide a cue for where to hold the diaphragm during insertion and a removal dome to facilitate removal. It is available at pharmacies or online without a prescription and can last up to 2 years.

### Cervical Cap

The only cervical cap available in Canada is the silicone FemCap which was approved by Health Canada in March 2009 (Figure 6).<sup>51</sup> This can be purchased online or with a prescription. Replacement is recommended every year. The cap comes in 3 sizes based on pregnancy history.

### Efficacy

Efficacy rates vary depending on the study and the methodology used. With perfect use, 6% of diaphragm users will experience an unintended pregnancy in the first year of use compared to 12% with typical use.<sup>12</sup> These rates are based on diaphragm use in conjunction with a spermicidal jelly or gel, which is no longer available in Canada. These numbers are not based on use with the lactic acid-based buffering gel (Caya gel, Contrigel) that is currently available in Canada for use with diaphragms. A study in couples using the SILCS diaphragm with either a nonoxynol-9 or an acid-buffering gel, reported a 6-month perfect use pregnancy rate of 7.9% (95% CI 11.7% to 14.0%).<sup>52</sup> With typical use, the 6-month pregnancy rate was 10.4% (95% CI 6.9% to 14.0%) which extrapolated to 12-month typical-use failure rate of 18.8% (95% CI 12.0% to 23.6%).<sup>52</sup>

There are no data on the efficacy/effectiveness of FemCap with the currently available acid-buffering gel (Caya gel or Contrigel). In a randomized study comparing the first model FemCap to the Ortho All-Flex diaphragm using 2% nonoxynol-9 gel, the 6-month pregnancy rates were 13.5% and 7.9%, respectively.<sup>53</sup> Therefore, a woman's willingness to accept a higher risk of an unintended pregnancy may be a determinant in her suitability for these barrier methods.

### Mechanism of Action for Diaphragm and Cervical Cap

The diaphragm and cervical cap serve as a physical barrier between sperm and the cervix and should always be used

**Figure 6. Cervical cap**



Produced with permission from FemCap Inc.

in conjunction with a gel that immobilizes or kills sperm. Currently, there is no nonoxynol-9 based jelly or cream available in Canada. Diaphragm or cap users should use an acid-buffering lubricant such as the SILCS diaphragm gel or Contrigel, which contain water, lactic acid, sodium lactate, cellulose, and sorbic acid. The gel forms a physical cellulose barrier in front of the cervix and lowers the pH of the vaginal fluid, thereby inhibiting sperm motility.

A diaphragm or cervical cap can be inserted up to 2 hours before intercourse. An additional application of an acid-buffering lubricant is required with each repeated act of intercourse or if it has been more than 2 hours since the device/gel was originally inserted and intercourse has not yet occurred. An applicator is necessary for this repeat insertion.

All devices should be left in place for at least 6 hours after intercourse. Diaphragms should not be left in longer than 24 hours after insertion in order to decrease the risk of TSS. If there has been sexual intercourse within the last 6 hours, the diaphragm can be kept in situ more than 24 hours (until at least 6 hours have passed since the last act of intercourse). The cervical cap can be left in place for up to 48 hours.

### Indications

Diaphragms and cervical caps may be suitable for women who do not wish to use hormonal contraception or for whom hormonal contraception is contraindicated. Diaphragms and cervical caps can also be used by breastfeeding women, by woman with a latex allergy or latex sensitivity, and those who are willing to accept a higher risk of an unplanned pregnancy taking into consideration the frequency of intercourse and the decrease in fertility associated with increasing age. The patient or her partner must be able to remove the diaphragm or cap.

## Contraindications and Cautions

A history of HIV infection or being at high risk of HIV were previously considered absolute contraindications to use of the diaphragm or cervical cap because they were used with nonoxynol-9 containing spermicides which themselves were associated with an increased risk of genital lesions and potential HIV transmission to uninfected sex partners.<sup>17</sup> Nonoxynol-9 spermicidal gels are no longer available in Canada, hence there are currently no absolute contraindication to the cervical cap or the diaphragm. Relative contraindications include latex allergy (does not apply to silicone diaphragms or caps), silicone allergy (for silicone diaphragms and caps), and history of TSS.<sup>17</sup>

A large cystocele, rectocele, or marked uterine prolapse may reduce the efficacy of the method.<sup>54</sup> The SILCS diaphragm is not recommended if a woman requires a diaphragm size  $\geq 85$  mm or  $< 60$  mm. After delivery or second trimester abortion, women should wait approximately 6 weeks until uterine involution is complete, and be refitted for a diaphragm or cap before re-using any of them. Refitting of the omniflex or arcing silicone diaphragms is also recommended after genital surgery or if the woman gains or loses 10 or more pounds.

## Non-contraceptive Benefits

While some studies have suggested a decrease in risk for developing some STIs and cervical intraepithelial neoplasia in diaphragm users,<sup>55,56</sup> others studies have not.<sup>57,58</sup> This has not been studied for the combination of diaphragm or FemCap and Caya gel currently available in Canada.

## Risks and Side Effects

Diaphragm use is associated with an increased risk of persistent or recurrent UTIs, possibly because of pressure from the diaphragm's rim on the urethra and the concurrent use of spermicides.<sup>59–61</sup> In a 6-month study comparing a 2% nonoxynol-9 based gel with the Ortho All-Flex diaphragm and the FemCap, there were significantly more UTIs in diaphragm users (12.4% vs. 7.5%), but the percentages of women who discontinued the study because they had 2 or more infections were around 1% in both groups.<sup>53</sup>

The risk of TSS is increased slightly in women who use vaginal barrier methods of contraception. The annual incidence is 2 to 3 cases per 100 000 women. These TSS cases would result in less than 1 death per year (0.18) for every 100 000 vaginal barrier users.<sup>62</sup>

## Myths and Misconceptions

### “All barrier methods protect against HIV infection.”

*Fact:* While male latex condoms protect against HIV infection, other barrier methods such as diaphragms and

the cervical cap provide limited HIV protection because the vaginal mucosa is still exposed.

### “Using a dia”phragm or cervical cap alone, without a gel that immobilizes or kills sperm, is as effective as using it with the gel.”

*Fact:* There are no conclusive studies indicating that a diaphragm or cervical cap is equally effective at preventing pregnancy if used with or without an acid-buffering gel or spermicide. Manufacturers continue to recommend that a gel that immobilizes or kills sperm be used with barrier methods such as the diaphragm and cervical cap.<sup>63</sup>

## Initiation

### Omniflex or arcing silicone diaphragm

A pelvic examination by a qualified health care provider is required for fitting the Omniflex or Arcing Silicone diaphragms (See Table 10). Fitting ring sets are available from the manufacturer. Fitting rings are produced in 5 mm increments (65–85 mm in diameter), but Milex Wide-Seal Silicone Omniflex diaphragms are available in sizes ranging from 60 to 95 mm. The woman should be fitted with the rim type (Omniflex or Arcing) type that she will ultimately use and may practice with it under the supervision of her health care provider.

### Cervical Cap

The cervical cap should fit comfortably over the cervix with the brim adhering to the vaginal fornices. (See Figure 7 and Table 11<sup>64,65</sup>)

Before a woman can successfully use the diaphragm or cervical cap, she will require detailed instructions for insertion (Tables 12 and 13), the opportunity to practice, and assistance/reassurance from her health care provider. Online videos can help to demonstrate how to insert the device. Providing information about the availability of, and indications for, emergency contraception, STI screening, and PEP is also important.

## Troubleshooting

If a diaphragm user is experiencing recurrent UTIs, a refit or change of rim type may help, or she may wish to try the cervical cap which has been associated with lower odds of UTIs than diaphragms<sup>66</sup> Post-coital voiding or antibiotic use may help.<sup>67</sup>

## CONTRACEPTIVE SPONGE AND SPERMICIDES

### Contraceptive Sponge

The sponge is a small, disposable, polyurethane foam device that is used intravaginally. The Today sponge, a pillow-shaped sponge containing nonoxynol-9, is the only contraceptive sponge available in Canada. It comes in one size only and is

**Table 10. Fitting for an Omniflex or Arcing Silicone Diaphragm<sup>64,65</sup>**

The correct diaphragm size can be estimated by the health care provider:

- inserting the index and middle fingers into the vagina until the posterior wall is reached (by middle finger),
- marking the point at which the index finger touches the pubic bone with the tip of the thumb, and
- removing the fingers, then placing rim of diaphragm on tip of the middle finger. The opposite side rim should be lying just in front of the thumb.

The health care provider then inserts a fitting diaphragm/ring into the correct position in the vagina.

The diaphragm should fit snugly with the posterior portion in contact with the posterior fornix, covering the cervix, with the anterior portion sitting behind the pubic bone.

When the diaphragm is properly fitted, a woman should not be able to feel anything in her vagina.

**Figure 7. Inserting the cervical cap**

Produced with permission from FemCap Inc.

available in pharmacies without a prescription. The concave dimple on one side fits over the cervix to provide a physical barrier to sperm and a woven polyester loop on the other side facilitates removal (Figure 8).

### Spermicides

Spermicides are composed of a spermicidal agent in a carrier that allows dispersion and retention of the agent in the vagina. Nonoxynol-9 (N-9) is available in Canada as a vaginal contraceptive film or as foam. Spermicides are available without a prescription. The use of a spermicide alone provides less effective contraception than using it in combination with a barrier method.

*Vaginal contraceptive film* is a 2-by-2 in. sheet of film containing 28% nonoxynol-9 (Figure 9). It must be inserted at least 15 minutes before intercourse in order to melt and disperse. If more than 3 hours have elapsed before intercourse, another film must be inserted.

**Table 11. Fitting for the FemCap cervical cap based on a woman's pregnancy history**

Small	22 mm	Never been pregnant
Medium	26 mm	Previous pregnancy (ectopic, miscarriage, Caesarean section)
Large	30 mm	Previous vaginal delivery

*Spermicidal foam* is effective immediately and for up to one hour after insertion. This preparation contains 12.5% nonoxynol-9 (Figure 10). It is inserted in the vagina using a supplied applicator. A repeat application is required prior to each additional act of intercourse.

### Effectiveness

The Today sponge has a perfect use failure rate of 9% in nulliparous women and 20% in parous women.<sup>12</sup> Typical failure rates are 24% in parous users and 12% in nulliparous women.<sup>68</sup> Effectiveness can be increased by using the sponge in combination with a male condom.<sup>68</sup> A review of clinical trials found that the sponge was less effective than the diaphragm in preventing pregnancy, and discontinuation rates were higher.<sup>69</sup>

Vaginal spermicides are among the least effective of all modern family planning methods.<sup>70</sup> Studies are difficult to compare and vary widely in size, focus, and quality.<sup>71</sup> A recent review concluded that the currently available studies are of insufficient quality to predict pregnancy rates with spermicide use.<sup>70</sup> Failure rates in the first year of use vary from 18% with perfect use to 28% with typical use.<sup>12</sup>

### Mechanism of Action

The contraceptive action of the sponge is primarily provided by the action of the impregnated spermicide, augmented by its ability to absorb and trap sperm. The sponge acts as a sustained release spermicidal reservoir for a period of 24 hours. Spermicides are composed of a spermicidal agent in a carrier that allows dispersal and retention of the agent in the vagina. Nonoxynol-9 is a surfactant that destroys the



**Table 12. Instructions for diaphragm use<sup>65</sup>****PRIOR TO INSERTION**

1. Wash hands. Check the diaphragm for holes, cracks, or tears by holding it up to the light
2. Check the expiration date of the Caya gel/Contragel
3. Insert the diaphragm no more than 2 hours before having sex
4. Prior to insertion of a diaphragm, put a teaspoon of acid-buffering gel into the bowl of the diaphragm and around the rim.

**INSERTION**

Press the rim together and push the diaphragm into the vagina as far as it will go. Feel the diaphragm to ensure that it covers the cervix. If uncomfortable, take it out and insert again.

**AFTER INTERCOURSE**

Keep in place for at least 6 hours after sex. It should not be kept in longer than 24 hours.

For multiple acts of sex, ensure the diaphragm is in the correct position and insert additional gel into the vagina before each act of sex.

**REMOVAL**

Wash hands. Insert a finger into the vagina, under the rim of the diaphragm, pull it down and out. The diaphragm should be washed with mild soap and clean water and dried after each use.

**Table 13. Instructions for cervical cap use****INSERTION**

1. Place 1/2 teaspoon of Caya gel in the groove between the dome and brim of the cervical cap. Place 1/4 teaspoon in the bowl of the device with a small amount over the brim.
2. Flatten the device by squeezing it. Place in the vagina with the bowl facing upward and the long brim directed toward the woman's back until it covers the cervix.

**REMOVAL**

1. Must be left in place for at least 6 hours after intercourse (no more than 48 h)
2. To remove the device, the woman should squat and bear down to bring the device closer to the fingers. The device should be rotated and removed by breaking the suction using the finger strap.

sperm cell membrane.<sup>48</sup> It is not a microbicide, and should only be used for contraceptive purposes, not as a lubricant or for STI prevention.

**Indications**

The sponge or the spermicide may be suitable for women who wish to avoid pregnancy but who also wish to and/or must avoid hormonal contraception, intrauterine contraceptives, or other barrier methods. Women who use the sponge or the spermicide alone should be aware of its higher failure rate compared to other methods of contraception. Some women choose the sponge because of its prolonged 24 hours of protection. The sponge or the spermicide may be used with other barrier methods to increase its effectiveness.

**Contraindications**

The only absolute contraindication to the sponge or the spermicide is being at high risk for HIV because nonoxynol-9 increases the risk of vaginal and cervical irritation or abrasions and thus, the transmission of HIV.<sup>17</sup>

Relative contraindications include:

- an allergy to nonoxynol-9,
- being HIV-positive or having AIDS due to increased risk of HIV transmission to uninfected sex partners,<sup>17</sup>
- use of antiretroviral therapy,<sup>17</sup> and
- a history of TSS.

The following conditions may not be compatible with the use of the sponge or spermicides:

- abnormal vaginal anatomy that interferes with satisfactory insertion of the spermicide or stable placement of the sponge,
- inability to use correct insertion technique,
- repeated UTIs, or
- full-term delivery within the past 6 weeks, a recent spontaneous or induced abortion, or vaginal bleeding, including menstrual flow (for sponges only)<sup>68</sup>

If there is a personal or medical need for highly effective

contraception, the sponge or the spermicide should not be the first contraceptive choice. The sponge and spermicides with nonoxynol-9 should also not be recommended to sex workers or to women with at increased risk of HIV infection.<sup>72</sup>

### Non-contraceptive Benefits

There is currently no evidence that the sponge or spermicides reduce the risk of acquiring STIs such as gonorrhea, chlamydia, or trichomoniasis.<sup>72</sup>

### Risks and Side Effects

The risk of TSS that is present with vaginal barrier use also applies to sponge use.<sup>62</sup> Sponge users must be aware of the symptoms and signs of TSS and recommended precautions.

Genital irritation associated with nonoxynol-9 can lead to easier transmission of HIV.<sup>16,72</sup> In a randomized study of sex workers in HIV endemic countries, there was a statistically increased risk of developing HIV in women who used spermicide more than 3.5 times daily and no reduction of HIV in those who used it less frequently.<sup>26</sup> The use of spermicides has also been associated with an increased risk of urinary tract infection.<sup>73,74</sup>

### Myths and Misconceptions

#### “Sponges and spermicides offer protection against STIs.”

*Fact:* Sponges are not microbicides. Nonoxynol-9 is not an effective microbicide; it may potentially damage vaginal mucosa and thus may enhance HIV transmission.<sup>16,72,75,76</sup> Spermicides have no protective effect against chlamydia, gonorrhea, or trichomonas infections.<sup>73</sup> Condoms should always be used for STI prevention. Although nonoxynol-9 increases the risk of HIV infection when used frequently by women at high risk of infection, it remains a contraceptive option for women at low risk.

#### “Use of a spermicide alone provides contraception that is as reliable as the use of a barrier method.”

*Fact:* Spermicides used alone have a substantially higher failure rate than other contraceptive methods<sup>12</sup> and quality studies of efficacy are lacking.<sup>70</sup>

#### “Nonoxynol-9 lubricated condoms are more effective than regular condoms.”

*Fact:* Condoms lubricated with or without nonoxynol-9 are similarly effective in preventing pregnancy.<sup>76</sup> The use of condoms lubricated with nonoxynol-9 is associated with an increased risk of UTIs.<sup>24</sup>

### Initiation of the Sponge

The contraceptive sponge (Today sponge) can be inserted up to 24 hours before intercourse. Protection begins immediately and lasts for 24 hours even with repeated acts

Figure 8. Contraceptive sponge



Produced with permission from FemCap Inc

Figure 9. Vaginal contraceptive film

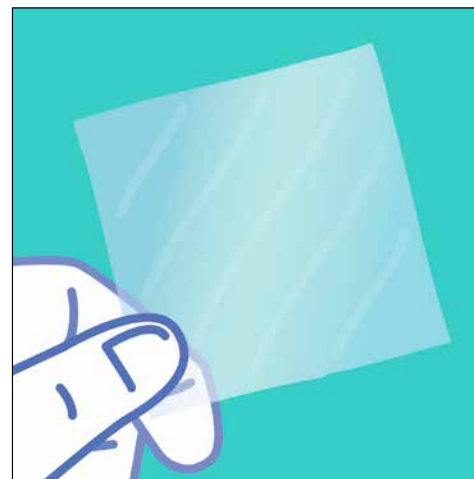


Illustration by Steve Cober

Figure 10. Spermicidal foam



Illustration by Steve Cober

**Table 14. How to use spermicides**

- Read and follow the package instructions
- Insert spermicide high in the vagina to cover the cervix
- Use the appropriate amount of spermicide
- Wait the recommended time between insertion and intercourse
- Insert an additional application of spermicide with every act of intercourse
- Do not douche for at least 6 hours after intercourse
- Always have additional supply of spermicides

of intercourse. It must be left in the vagina for at least 6 hours after the last act of intercourse but should not remain in the vagina for more than 30 hours total.

Prior to using the sponge, women should wash their hands. The sponge should be moistened with 2 tablespoons of water and squeezed once in order to activate the spermicide. With the dimpled side of the sponge facing the cervix, the sponge is folded upward and inserted deep into the vagina. The sponge must cover the cervix and the loop should be on the bottom to facilitate removal. The sponge must be inserted before the penis enters the vagina. The sponge must be left in place for at least 6 hours after the last act of intercourse, and then can be removed by pulling on the loop.

### Initiation of Spermicides

It is important to read and follow the instructions carefully, especially the length of time from insertion of the spermicide to intercourse, and the duration of effectiveness (See Table 14).

Spermicide users should be counselled about the use of emergency contraception in the event that they fail to use the spermicide or it was not used correctly.

### Troubleshooting

Inserting a contraceptive sponge or a spermicide should be practised before coitus takes place, in order to increase comfort with use. If genital irritation or unpleasant odour occurs, infections such as STIs, vaginal moniliasis, and bacterial vaginosis should be ruled out.

### Summary Statements

27. Latex condoms, used consistently and correctly, will provide protection against pregnancy (II-2) and sexually transmitted infection (STIs), including human immunodeficiency virus infection (II-1). However, no barrier contraceptive method can provide 100% protection from all STIs. (III)
28. Polyurethane and other non-latex male condoms have a higher incidence of breakage and slippage than latex condoms; hence, the protection they

provide against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection is inferior to that of latex condoms (I). Polyurethane and polyisoprene condoms remain important options for contraception and reduction of STIs in the presence of latex allergies. Lambskin condoms do not protect against HIV infection. (III)

29. The effectiveness of barrier methods can be complemented by the use of emergency contraception. (III)
30. The contraceptive sponge and spermicides used alone are not highly effective contraceptive methods; their effectiveness may be enhanced when used in combination with another contraceptive method. (II-2)
31. Contraceptive products containing nonoxynol-9 may cause vaginal epithelial damage and increase the risk of human immunodeficiency virus infection. (I)

### Recommendations

27. Health care providers should promote the consistent and correct use of latex condoms to improve protection against pregnancy, human immunodeficiency virus infection, and other sexually transmitted infections. (II-2A)
28. Health care providers should educate women and men about the correct use of barrier methods. They should emphasize the need for dual protection against pregnancy and infections. (II-2B)
29. Women who use barrier methods of contraception should be counselled about emergency contraception. (III-B)
30. The use of spermicide-coated condoms should no longer be promoted. (I-A)
31. Diaphragms and cervical caps should continue to be available in Canada and appropriate training should be available for health care providers to become proficient in fitting diaphragms. (III-C)
32. Nonoxynol-9 products should not be used to reduce the risk of sexually transmitted infections and human immunodeficiency virus (HIV) infection and should not be used by women at high risk for HIV transmission. (I-A)

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