

Safer is Sexy

Resource Kit for Professionals
Promoting Use of the FC2 Female Condom[®]



The Female Health Company

www.fc2.us.com

The Female Health Company would like to thank the following people and organizations for their contribution to the Safer is Sexy Facilitator Training Manual and accompanying training materials:

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January 2011

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Welcome to the Safer is Sexy Resource Kit

Welcome to the FC2 Safer is Sexy Resource Kit for professionals. The purpose of this Resource Kit is to better prepare providers with the skills and knowledge needed to promote the proper use of FC2.

The FC2 female condom, approved by the FDA, is now available in the United States. FC2 offers women a choice, that they can initiate, to provide dual protection against unintended pregnancy and sexually transmitted infections (STIs), including HIV/AIDS.

FC2 is the second generation female condom to FC1. FC2 was developed to take the place of FC1, providing the same safety and efficacy during use, but at a lower cost. The effectiveness of FC2 was studied by comparing FC2 performance to FC1, the studies showed FC2 to be comparable to FC1. Certain other studies have shown that having the FC female condom available allows women and men to access more prevention options and results in an increase in protected sex acts and a decrease in STIs, including HIV/AIDS.

FC2 has high acceptability among both men and women in many countries. FC2 has the same design and instructions for use as the original FC female condom. The material has been changed to improve affordability, while maintaining the high quality, reliability and features of FC1. FC2's sheath, with its outer ring, is made from a synthetic nitrile. The inner ring aids insertion and helps to secure the device in place during intercourse while the softer outer ring remains outside the vagina.

The stress of unintended pregnancy and the increasing toll of Sexually Transmitted Infections (STIs), including HIV, on women demonstrate the need for service providers to counsel women and couples on the entire range of protective options available to them.

The way in which FC2 is presented to potential users is essential to its acceptance. We hope this tool will help you, the provider, empower women and their partners to try and properly use FC2.

Thank you for joining us! - The Female Health Company

How to Use this Resource Kit

This Resource Kit is divided into two main sections.

- Section I is for providers. This section includes the basics about FC2, HIV/STI facts, FC2 proper use, and provider skill-building resources for working with clients.
- Section II includes resources that providers can copy and distribute to clients or have available at health fairs.

Section I

Resources for Providers

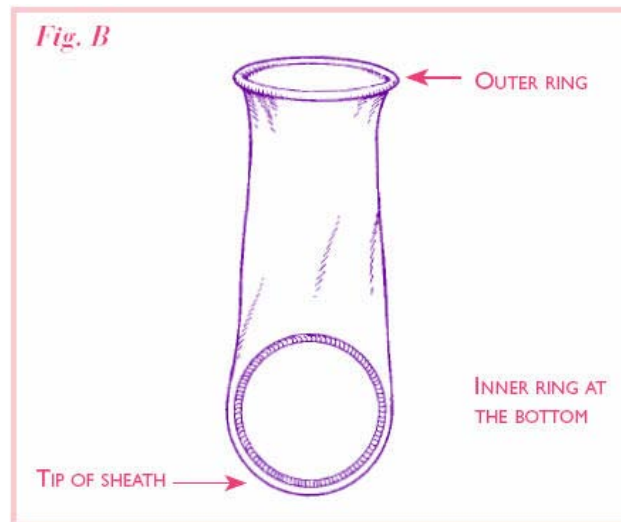
General Introduction to FC2

The Look



What is FC2 Female Condom®?

- FC2 is a strong, soft, nitrile sheath or pouch 17 cm (6.5 inches-the same as the male condom) in length. Nitrile polymer (non-latex), is thin and strong, and heats to body temperature
- FC2 Is worn by the woman during sex and placed up by the pubic bone
- FC2 can be inserted prior to sex since it is worn by the woman and the man does not need to be erect
- FC2 cannot be used simultaneously with a male condom
- FC2 contains a silicone-based lubricant on the inside of the condom, but additional lubrication can be used. FC2 does not contain spermicide.



How FC2 Works

- FC2 has a flexible ring at the closed end of the pouch with a slightly larger ring at the open end.
- At the closed end of the sheath, the flexible ring is inserted into the vagina to hold the female condom in place.
- At the open end of the sheath, the ring stays outside the vulva at the entrance to the vagina. This ring acts as a guide during penis penetration and it also prevents the sheath from bunching up inside the vagina.

Why FC2 is important?

- Female condoms work to prevent pregnancy and STIs, including HIV, by lining the inside of the vagina, preventing skin touching skin.
- They collect pre-cum and semen when a man ejaculates, keeping sperm from entering the vagina and thereby preventing pregnancy and reducing the risk of STIs.
- Women have options available to them to increase protected sex acts and decrease the transmission of STIs and unintended pregnancy. Providers play an important role in presenting all the options of protection to their clients.

Who Can Use FC2?

- Women who are concerned about unintended pregnancy and STIs.
- Women who are menstruating.
- Women who have recently given birth.
- Women who have a retroverted uterus.
- Women who have had a hysterectomy.
- Women who are peri and postmenopausal.
- Women who are allergic/sensitive to latex.

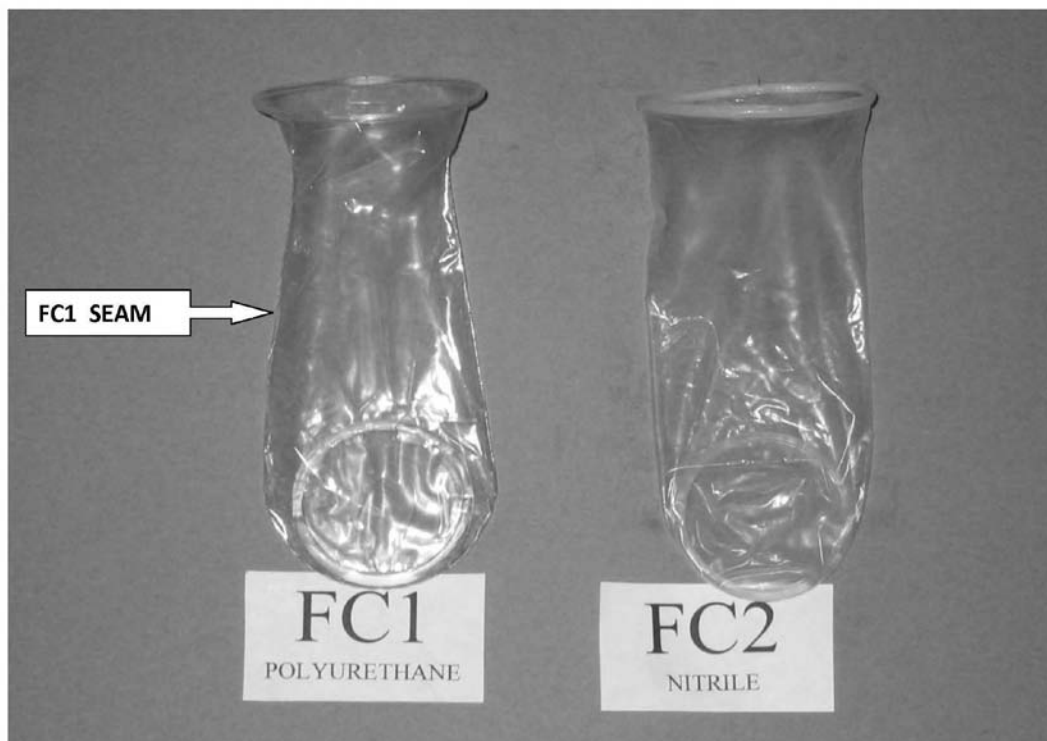
How Effective is FC2?

Studies show the clinical effectiveness of FC2 is equivalent or comparable to FC1. Over 16 years of studies have shown the female condom is an effective barrier against many common STIs, including HIV.

- It is estimated that correct and consistent use of the female condom for one year with an HIV+ partner could reduce a woman's risk of acquiring HIV by 90%.
- Studies in the U.S. and internationally have found that the prevalence of STIs decline and the rate of protected sex acts increase when female condoms are made available alongside the male condom.

How is FC2 different or the same as FC1?

FC1	FC2
Made of polyurethane	Made of Nitrile polymer
Has a seam	No seam
Outer ring is polyurethane	Outer ring is rolled Nitrile polymer
Design	Same design
Dimensions	Same dimensions
Insertion	Same method of insertion
Safety and Efficacy	Same safety and efficacy
Acceptability	Same acceptability



HIV/STI/Unintended Pregnancy Statistics

HIV and AIDS Today

More than 25 years into the AIDS epidemic, HIV infection continues to exact a tremendous toll in the United States and around the world. According to the Centers for Disease Control (CDC), in the United States:

- Every 9 1/2 minutes, on average, someone is infected with HIV.
- More than 1 million people in the U.S. are living with HIV.
- Current estimates indicate that of those 1 million people living with HIV, 1 in 5 are unaware of their HIV-positive status.

HIV/AIDS in Women

Infection rates for women around the world continue to increase. U.S. Centers for Disease Control and Prevention states "if new HIV infections continue at their current rate worldwide, women with HIV may soon outnumber men with HIV". The number of women living with HIV in the United States has tripled in the last two decades. Today in the U.S. women account for more than one quarter of all new HIV/AIDS diagnoses, with women of color being especially affected by HIV and AIDS.

Furthermore:

- Black and Hispanic women accounted for 81% of the women living with HIV/AIDS in 2005 who acquired HIV through heterosexual contact and;
- Heterosexual intercourse accounts for most HIV diagnoses among women (70% in 2006, CDC).

Women and “No Identified Risk”

Information on HIV risk is typically provided to health care providers during routine medical histories and/or in the course of an HIV testing counseling session. For the purposes of HIV surveillance data each reported case of new HIV infection is counted only once in a list of exposure risk categories (i.e., MSM, IDU, MSM/IDU, and Heterosexual). A single risk exposure category is assigned based on a classification system in accordance with CDC-defined hierarchy of risk exposure categories.

For example, if a woman reports having heterosexual contact and also reports IV drug use, the risk factor would be classified as IV drug use.

Therefore, an individual with HIV for whom all but heterosexual HIV risk has been ruled out can ONLY be classified as heterosexually exposed if that person knows their partner's risk status. For example, if a woman states that she was in a monogamous relationship and she believes her partner to have no risk she would be classified as having no identified risk because it is based on the risk factor of her partner.

In reality, most women contract HIV heterosexually when they believe they are in a monogamous relationship. But if a newly diagnosed woman can't identify her male partner's HIV status or “high-risk” behavior (e.g. male to male sexual contact or injection drug use), and other means of transmission are ruled out, the CDC surveillance system automatically places her in a generic category labeled “no identified risk” (NIR).

Impact on Women

- Women are often unaware of the risky sexual behavior of their male partner(s).
- Women are two times more likely to be infected by a husband or steady partner than by a casual partner.
- The impact of HIV is not reflective of the prevention needs of women, as public health policy regarding prevention for HIV is based on these classification categories.
- It is estimated that 40-60% of all women testing positive for HIV in the U.S. are classified as NIR.

STIs - The Big Picture

Sexually Transmitted Infections (STIs), including Chlamydia, Gonorrhea, Syphilis, Herpes, and Human Papillomavirus (HPV), substantially impact public health in the United States. The relationship between STIs and HIV is significant, making primary STI prevention a secondary prevention method for HIV. Consider the following:

- More than half of all people will have an STI at some point in their lifetime.
- One in two sexually active persons will contract an STI by age 25.
- The estimated number of people living in the U.S. with a viral STI is over 65 million, with 19 million new cases in the U.S. each year. This is the highest rate in the industrialized world.
- It is estimate that each year in the U.S. untreated STIs cause at least 24,000 women to become infertile.

Women and Biological Vulnerability

The biological risk of contracting STIs and HIV through heterosexual intercourse is greater for women than for men for several reasons. Women have a larger susceptible surface area, including tissues of the vagina as well as the cervical epithelium. Women are also more likely to experience asymptomatic STIs than are men and experience even greater risk due to:

- Fluctuating hormone levels;
- Changes in acidity and alkalinity in the vagina, and;
- HIV having an easier time surviving in the vagina than on the surface of the penis.

Unintended Pregnancy

An unintended pregnancy is a pregnancy that is either mistimed or unwanted at the time of conception and is a core concept in understanding the fertility of populations and the unmet need for contraception. Unintended pregnancy is associated with an increased risk of morbidity for women and with health behaviors during pregnancy that are associated with adverse effects. For example, women with an unintended pregnancy may delay prenatal care, use alcohol or other drugs, and/or have unprotected sex, which may adversely affect the health of the infant and the mother. Women of all ages may have unintended pregnancies, and in the United States, nearly half of all pregnancies are unintended. In fact:

- By age 45, more than half of U.S. women have had one or more unintended pregnancies.
- Of the nearly 50 million sexually active 18-44 year-old women in the United States today, 28 million are at risk for unintended pregnancy.
- According to the Centers for Disease Control and Prevention, between 2000 and 2005, births among women ages 45 to 54 rose by 45%.
- A National Center for Health Statistics survey indicates that 40% of pregnancies in women age 40 or over are unintended.

Notes:

Female Anatomy and Physiology

External Female Anatomy

Major external anatomy points, as they relate to FC2 include:

The Labia

- Also known as the "lips," the labia comprises the inner and outer lips of the vulva.
- The lips are spread when inserting FC2.

The Clitoris

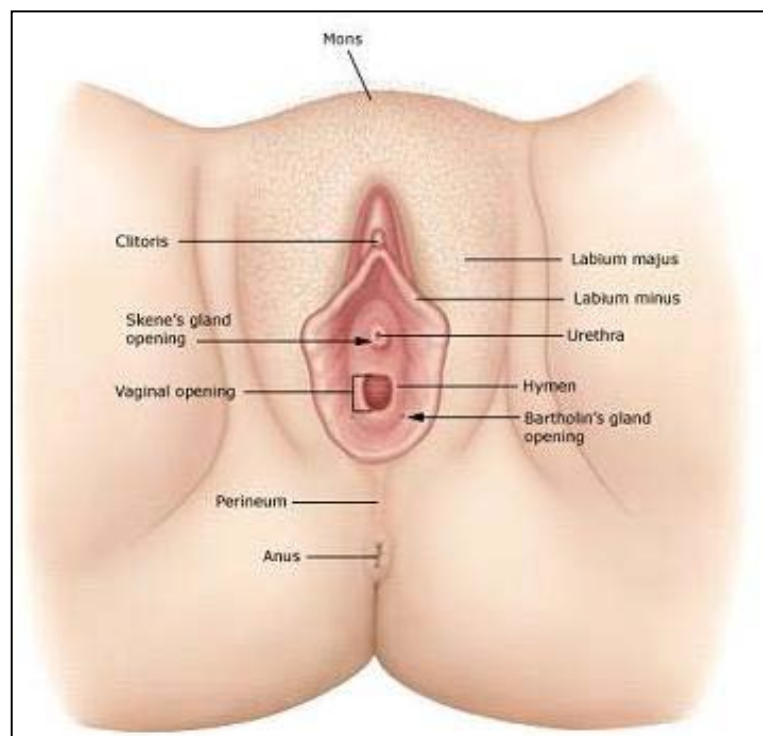
- This small body of smooth spongy tissue is highly sexually sensitive, containing around 8,000 nerve endings tightly packed together. During sexual excitement, the clitoris may become erect and the hood will retract to make the clitoris more accessible.
- **FC2 may provide clitoral stimulation during use as the outer ring sometimes rubs against the clitoris.**

The Urethra

- Show the urethra, explaining that inserting FC2 will not interfere with normal bodily functions such as urination.

The Vaginal Opening

- Show the vaginal opening, explaining that **this is where FC2 is inserted** and is also where the penis enters during sexual intercourse.

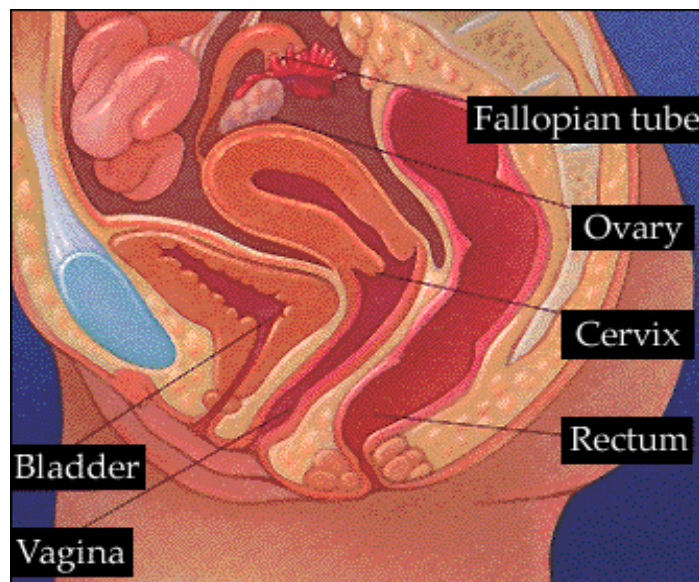


Internal Female Anatomy

Major internal anatomy points, as they relate to FC2 include:

The Vaginal Canal

- The vagina is a pouch that forms the vaginal canal.
- It extends from the vaginal opening to the cervix, (the opening to the uterus).
- The penis is inserted into the vaginal canal during sexual intercourse; the vagina is also the birth canal through which the baby passes during child birth.
- The average vaginal canal is three inches long, possibly four in women who have given birth.
- FC2 lines the vaginal canal and adheres to the vaginal walls.



The Cervix

- The cervix is the lower, narrow part of the uterus (womb).
- The cervix opens into the vagina, which leads to the outside of the body.
- When inserted properly FC2 covers the cervix.

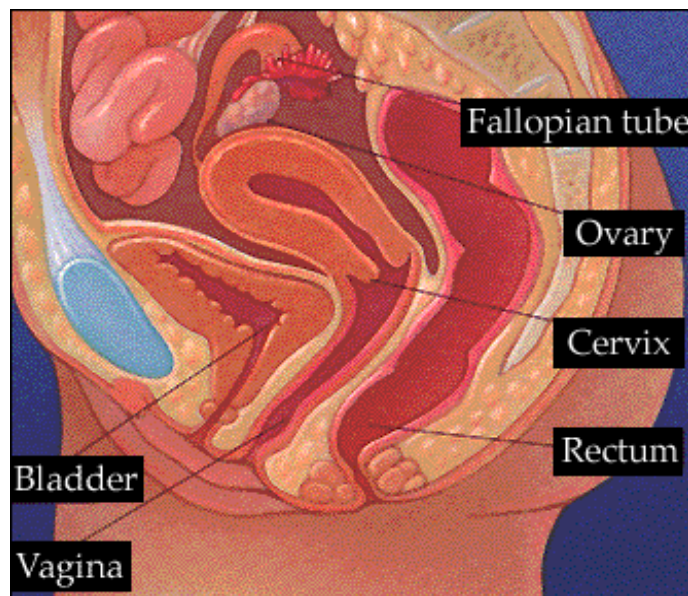
Pubic Bone

- The pubic bone is the front bottom of the three principal bones composing either half of the pelvis.
- The inner ring of FC2 goes behind the pubic bone, anchoring it into place.

Note: Sometimes when using FC2 the woman may complain that it doesn't feel right or is uncomfortable. Typically, this feeling is the direct result of the woman experiencing one or two insertion errors.

1. The first potential problem: Instead of the inner ring resting against the cervix the inner ring is rubbing or hitting against the cervix and all the woman needs to do is insert her finger and adjust the inner ring.
2. The second potential problem: The inner ring is not snugly behind the pubic bone. All the woman needs to do is simply re-insert, being sure to pop the inner ring behind the pubic bone.

Remember- Pop behind the pubic bone and/or adjust the inner ring.



Female Condom and Proper Use

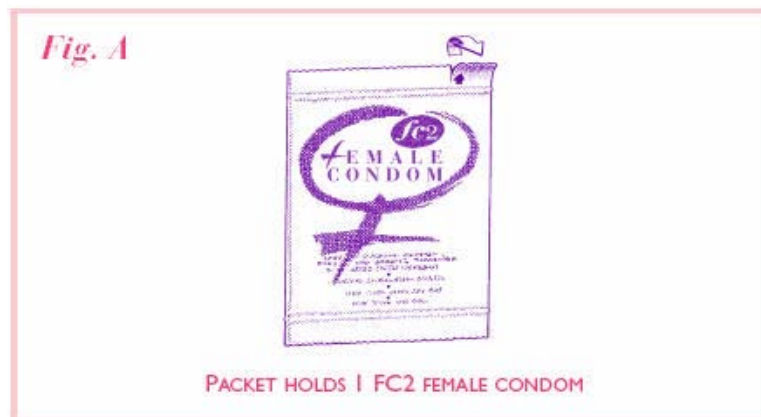
Preparing for Use

The following steps provide a useful guide for preparing to insert the female condom:

- Start with one FC2 package.
- As with the male condom, it is important to check the expiration date prior to opening FC2.

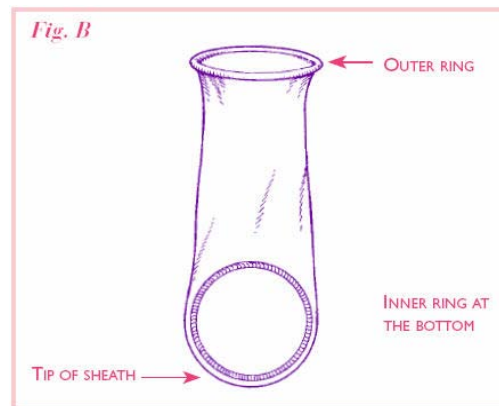
To Open The Packet:

- Locate arrow at tear notch on upper right-hand corner and tear open Fig. A.
- Rub the outside of the pouch together to be sure the lubrication is evenly spread inside the pouch from the bottom to the top.
- Take out FC2 and look at it closely to make sure it is not damaged.

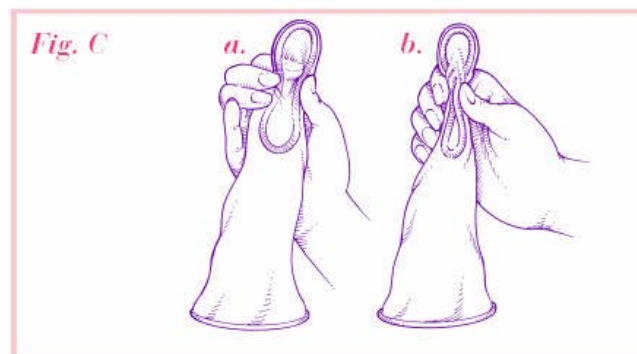


To Insert the FC2 Female Condom:

- Find a comfortable position. Try standing with one foot up on a chair, or sit with knees apart, or squat down.
- Be sure the inner ring is at the bottom, closed-end of the pouch Fig. B.

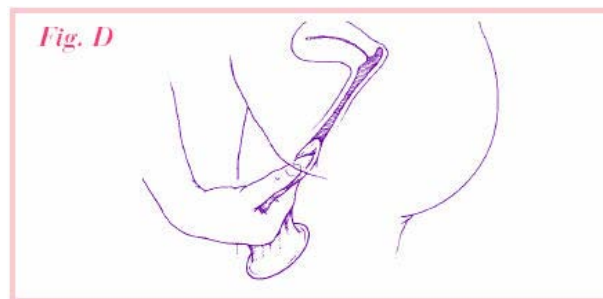


- Hold the pouch with the open end hanging down. While holding the outside of the pouch, squeeze the inner ring with your thumb and middle finger.
- Place your index finger between the thumb and middle finger and keep squeezing the inner ring Fig. C (a).
- Or just squeeze - whichever is easier for you Fig. C (b).

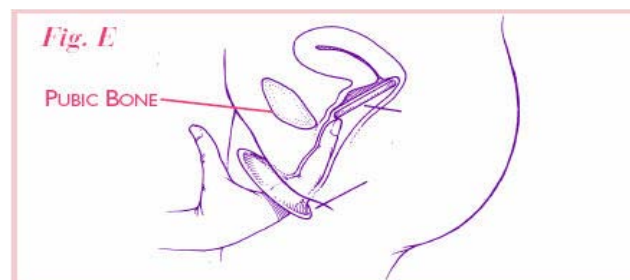


To Insert the FC2 Female Condom, cont'd:

- Still squeezing the FC2 Female Condom with your other hand, spread the lips of the vagina as if you were getting ready to insert a tampon.
- Insert the squeezed FC2 Female Condom as shown in Fig. D.
- Take your time. If the FC2 Female Condom is slippery to insert, let it go and start over.

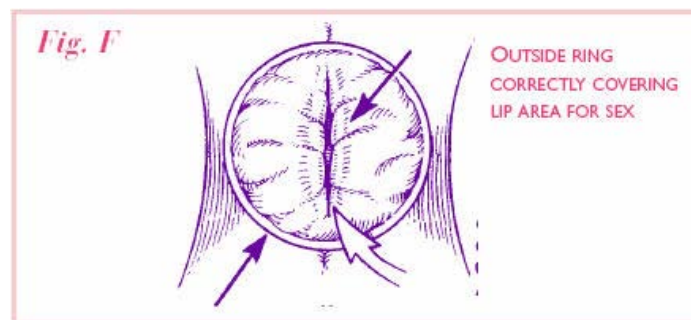


- Now push the inner ring and the pouch the rest of the way up into the vagina with your index finger. Check to be sure the inner ring is up just past your pubic bone Fig. E.
- You will feel your pubic bone by curving your index finger when it is a couple of inches inside the vagina.
- This step may be hard to do on the first or second try because the FC2 Female Condom is lubricated.
- Take your time and push the closed end of the FC2 Female Condom up to where you can feel the pubic bone.



To Insert the FC2 Female Condom, cont'd:

- Make sure the FC2 Female Condom is inserted straight (not twisted) into the vagina.
- It is also important that the outside ring lies against the outer lips of the vagina as shown in Fig. F.
- About one inch of the open end will stay outside your body. FIG. F. While this may look unusual, this part of the FC2 Female Condom helps protect you and your partner during sex. Once the penis enters, the vagina will expand and the slack will decrease.

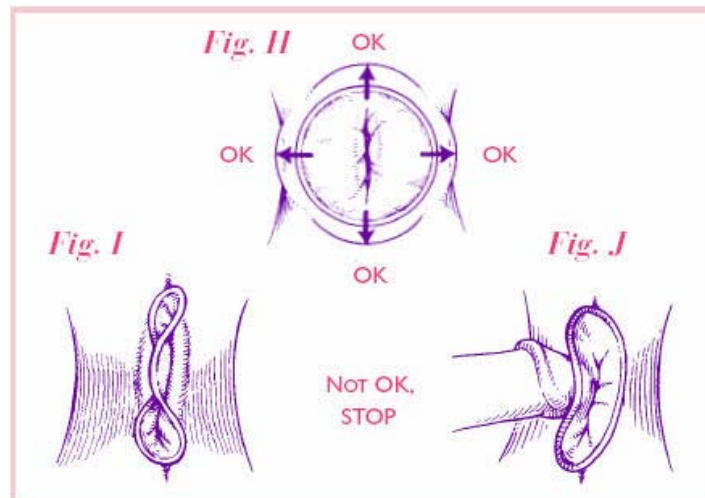


- Until you and your partner become comfortable using the FC2 Female Condom, use your hand to guide the penis into the vagina. See Fig. G.
- After two or three times, you should become familiar with using the FC2 Female Condom and should hardly notice the pouch or the outer ring during sex.



During Intercourse

- You may notice that the FC2 Female Condom moves around during sex. See Fig. H.
- Movement side-to-side of the outer ring is normal.
- Sometimes the FC2 Female Condom may slip up and down in the vagina, "riding" on the penis. Both the vagina and the penis are still covered.
- However, if you notice the FC2 Female Condom is slipping out of the vagina, STOP, remove, and insert a new FC2 Female Condom.
- If you begin to feel the outer ring being pushed into the vagina, STOP (Fig. I). Or, if the penis starts to enter underneath or beside the pouch, STOP (Fig. J). Take out the FC2 Female Condom. Put in a new FC2 Female Condom. Make sure the outside part lies over vagina.



Potential Failure Problems:

The following are problems that have been reported when using the FC2 during sex:

1. the penis can push the FC2 condom (including outer ring) inside the vagina;
2. the penis enters the vagina without FC2 protection;
3. the FC2 female condom breaks during use;
4. the FC2 slips completely out of the vagina.

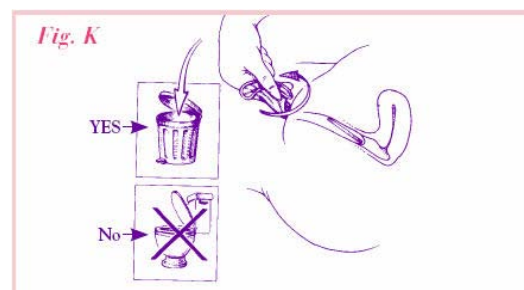
In each of the scenarios described above, the risk of vaginal exposure to semen is increased. If any of these occur, you should dispose of that female condom and use a new one.

How to fix problems

- * Hold the outer ring in place when you insert the penis. This will stop the FC2 from getting pushed inside the vagina AND will also stop the penis from entering on the outside of the FC2. (Once the penis is inserted- you can let go. You DO NOT need to hold the FC2 in place during sex).
- * If the FC2 is slipping too far out of the vagina (riding on the penis), or if the outer ring is being pushed inside the vagina during sex, add more lubricant to the inside of the FC2 or to the tip of the penis. .
- * Remember to be careful when handling FC2. While rips and tears are reported in FC2 less than 1% of the time, care should always be taken (e.g. do not open packet with scissor, handle appropriately with long nails) when handling any type of condom.

After Intercourse

- To take out the FC2 Female Condom, squeeze and twist the outer ring to keep the sperm inside the pouch. Pull out gently. Throw away in a trash can. Do not flush. Do not reuse. Please see Fig. K.



Talking with Clients - Tips for Success

When discussing the use of FC2, there are several reoccurring themes that arise. Here are some tips to addressing those themes:

1. Some women are **afraid** to use FC2 because they are unaware of their **anatomy**.
 - Approach: Providers educate their clients about general female anatomy as it related to FC2 insertion and use. Focus on cervix, pubic bone, vaginal canal, vaginal opening, and clitoris.

2. Some women are not comfortable **touching themselves**, but are too embarrassed to say this.
 - Approach: Assessment of a clients comfort level with using FC2 by discussing feelings regarding tampon use, looking at, and/or touching one's own vagina can help address insertion related issues. If a woman is absolutely not going to touch herself or is not comfortable inserting her finger into her vagina in order to adjust the inner ring, you can suggest that her partner put the FC2 in for her as part of foreplay. If you client is uncomfortable with this option as well, then FC2 is not a realistic option for her. See 3-time approach with client on page 27.

3. Some women may say "yes I understand how to use the female condom" or say they'll **try it** and then **do not**.
 - Approach: Allow client to feel FC2 to become familiar with it.
 - Approach: Provide thorough instructions for insertion and demonstrate these steps on a pelvic model. Diagrams and/or anatomical models should be used to illustrate correct use of FC2. They can also be a valuable tool for illustrating problems that may be encountered when using FC2, allowing you to demonstrate the appropriate way to combat/ correct the issue.

- Approach: Provide the client a pelvic model and an opportunity to practice insertion on the model with you, the provider, walking her through the steps and providing a proper insertion check.
 - Approach: Encourage the client to try practicing insertion first without a partner and then with a partner.
 - Approach: Reassure clients that it may take several attempts before they can use this method confidently with a partner for sex, but that after practicing most women are comfortable with FC2.
4. Some women are just too **embarrassed** to ask questions, if they have them.
- Approach: Provide counseling in either individual or small group sessions with other women providing peer support.
 - See 3-time approach with client on page 27.
5. Some women are just afraid of its size and feel:
- Approach: Counsel the client that FC2 may be slippery to work with at first, but becomes easier with practice.
 - Approach: Providers can unroll a male condom and hold it next to FC2. They are the same size.
6. Some women have heard it's **noisy or the condom can slip** into the vagina.
- Approach: Lubricant is a key problem solver for many mechanical use challenges for FC2. Most problems people have using FC2 can be fixed by adding lubricant (oil or water-based) to the inside of the condom or to the penis. Add more lubricant if:

- FC2 is being pushed inside the vagina
- FC2 is riding on the penis (i.e. being pulled in and out with the penis)
- There is noise

7. Some women might want to know **why** you are even talking with them about the female condom.

- Approach: Tell clients you are empowering them with another option. A choice. Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including HIV/AIDS, if used correctly. And FC2 Female Condom can also protect yourself and your partner.
- Approach: Remind the client that FC2 cannot be used simultaneously with a male condom.

The most important tips to remember:

- Difficulty with insertion is one of the most common barriers to use with FC2. However, studies show insertion difficulties can be overcome with **practice** and instruction.
- Basic knowledge of female anatomy and enough opportunity to **practice** are important indicators for success with using FC2.
- Insertion **practice**, first without and then with a partner, can increase acceptability and sustained use of FC2.
- Providing clients with the following can also help address use-related challenges:
 - Tips for insertion of FC2.
 - Insertion checks on vaginal models.
 - Emphasis on practice.
- Providing the following tips to clients helps with any use related issues:
 - If FC2 feels dry during use, add a few drops of **lubricant** to the partner's penis or inside the condom.

- Gently hold the outer ring of the condom against your body.
- Guide the penis into the opening of FC2.
 - * Note - once the penis is in place you can let go... you **DO NOT** need to hold FC2 while you are having sex!

A Brief Three-Time Approach with Clients.

The 3-time approach with clients:

1. While you are talking with the client hand her a lubricated FC2 and ask her to: hold it, feel it, squeeze it while you are talking, pinch it, rub it against her arm. Let it warm up against her skin. Show her how it is clearer, more pliable, it has heated up against her skin.
 2. Allow the client several opportunities to do a demonstration in your office, using her hand or a pelvic model. Next suggest that she go home and "try it". Put it in, walk around with it. Practice inserting while in difference positions. Figure out which position feels best.
 3. Insert for sex.
- * FC2 is not just for women- don't forget to promote the product to your male clients.... Give them the same opportunity to feel the product- to get comfortable with it, so they can take it home to their partners.

Talking with Clients

FC2 Promotional Messages

FC2 can be an exciting and sexually satisfying alternative for couples. Below is a list of promotional messages that you can discuss with clients.

- FC2 can increase a woman's sense of empowerment as she is taking the initiative to protect herself and her partner.
- FC2 Increases sexual stimulation because the material adjusts to body temperature and stays warm.
- External ring rubs against clitoris and increases pleasure for many women.
- Men do not have to have/ maintain an erection to use FC2. FC2 is a good option for men who are unable to maintain an erection with the male condom.
- Men do not have to withdraw right after ejaculation, which may lead to more intimacy when using FC2.
- FC2 can be inserted ahead of time so there are no interruptions to "spoil the mood".
- Insertion of FC2 can be incorporated into sexual play, the partner can watch as it is put in place OR can help insert it.
- FC2 is a great choice for people with sensitivities to latex.
- FC2 can be used with any kind of lubricant (water or oil-based lubricants).
- FC2 provides an option for those times when a couple does not want to use the male condom (NOTE: Clients should never use a male condom and FC2 at the same time).
- FC2 is not tight or constricting around the penis; some men prefer FC2 to the male condom.
- The inner ring of FC2 can stimulate the tip of the penis during intercourse.
- The man does not have to worry about wearing a condom.
- FC2 provides effective dual protection, reducing the worry during sex about pregnancy and STIs/HIV.
- Increased sensation compared to latex male condom because nitrile is very thin.

Eroticize It

Service providers have the opportunity to unveil the mystery of FC2 as a method used to enhance sexual pleasure. Having access to risk reduction methods that do not interfere with sexual pleasure for women and their partners are indicators of continued use of these methods. A fundamental ingredient of good sexual health is women's sense of entitlement to sexual pleasure. Many of the pleasure aspects of using FC2 may include enhanced intimacy, spontaneity and increased sensation. Women's sense of control over their bodies is another indicator of sexual health and their ability to initiate sex contributes to this sense of control. For many women FC2 is a catalyst for sex because the act of insertion is a signal to partners of their interest in having sex.

He may use it if...

Often providers are discussing the female condom with the female clients, but the provider can provide the female client with talking points or selling points she can use with her male partner in order to get him to use it. In addition, with more media attention to erectile dysfunction and the number of men that lose their erection when putting on a male condom, men may be more likely to try a female condom because it is not constricting to the penis.

Talking with Clients Negotiation Skills Transfer

Negotiating FC2 Use

Including negotiation when counseling women regarding use of FC2 may lead to greater acceptability and use. Women who have difficulty negotiating safer sex may benefit from group education sessions with other women. In peer support groups women can offer each other emotional support and examples of success stories in negotiating safer sex. They can learn and adopt strategies, language and tools that empower them.

In one to one sessions in clinic settings, service providers will need to provide opportunities for clients to practice negotiation techniques and give them the opportunity to respond to negative reactions. This may include providing:

- Opportunities for role plays.
- Information on ways to present FC2.
- Information on when to present FC2.
- Information on how to make FC2 sexy and fun.
- Pamphlets, videos and information for their partners.

Talking with Clients

Tips for Communicating with your partner about sex

The timing, place, knowing what you want to say and how you say it are key to effective negotiation. Know what to say and do should the outcome be negative such as aggression or violence.

- Choose a relaxing environment in a neutral location, preferably outside the bedroom, where neither of you feel pressured.
- Do not wait until you or your partner is sexually aroused to discuss safer sex. In the heat of the moment, you and your partner may be unable to talk effectively.
- Use "I" statements when talking. For example, "I would feel more comfortable if we used a condom".
- Be a good listener. Let your partner know that you hear, understand, and care about what she/he is saying and feeling.
- Be "ask-able" - let your partner know that you are open to questions and that you won't jump on him/her or be off ended by questions.
- Be patient and remain firm in your decision that talking is important.
- Recognize your limits. You don't have to know all the answers.
- Understand that success in talking does not mean one person getting the other person to do something. It means that you have both said what you think and feel respectfully and honestly.
- Avoid making assumptions. Ask open-ended questions to discuss expectations, past and present sexual relationships, contraceptive use, HIV testing, etc. For example, "What do you think about us both going for an HIV test?"
- Ask questions to clarify what you believe you heard. For example, "I think you said you want us to use condoms. Is that right?"
- Avoid judging, labeling, blaming, threatening, bribing or manipulating your partner.
- Don't let your partner judge, label, threaten, coerce or bribe you.

Other Resources for Providers

Since the use of pelvic models is so important in teaching clients the proper use of FC2, included here are a few resources of where to purchase a pelvic model and penis.

Model	Description	Known Purchase Locations
	Pelvic Model/ Penis Kit	B & L Silicones- BSilicones@hotmail.com
	Female Pelvis Contraceptive Model	http://www.a3bs.com/index.html http://www.healthedco.com/ http://www.1cascade.com/ http://www.totalaccessgroup.com
	Female Contraceptive Model	http://www.healthedco.com/ http://www.enasco.com/ http://www.schoolkidshealthcare.com/
	Female Condom Training, Birth Control Model	http://www.buyamag.com/
	Female Contraceptive Sponge Condom Training Model	http://www.buyamag.com/ http://www.globalprotection.com/
	LINDI Pelvic Model	http://www.plannedparenthood.org/ http://www.totalaccessgroup.com

Section II

Resources for Clients

The Female Condom 2 (FC2) Quick Tips

Description

- FC2 is a strong thin and flexible nitrile sheath or pouch 17 cm (6.5 inches - the same length as a male condom) in length.
- FC2 is worn by the woman during sex.
- FC2 has a flexible polyurethane ring at the closed end of the pouch (the end that is inserted into the vagina) and a soft nitrile ring at the open end of the pouch (the end that remains outside of the vagina.)
- There is silicone based lubricant on the inside of the condom, additional lubrication can be used.
- FC2 works to prevent pregnancy and STIs including HIV, by lining the vagina.

Effectiveness

- Studies show the clinical effectiveness of FC2 is equivalent or comparable to FC1.
- Over 16 years of studies have shown FC1 to be an effective barrier against unintended pregnancy and STIs, including HIV.
- FC2 is a woman-initiated method of preventing both pregnancy and STIs, including HIV.

Benefits

- FC2 can increase a woman's sense of empowerment as it is worn by the woman and offers effective dual protection.
- The man does not have to have an erection for FC2 to be used which can enhance couple intimacy.
- FC2 offers another option to the male condom and is a great choice of people with latex sensitivity.

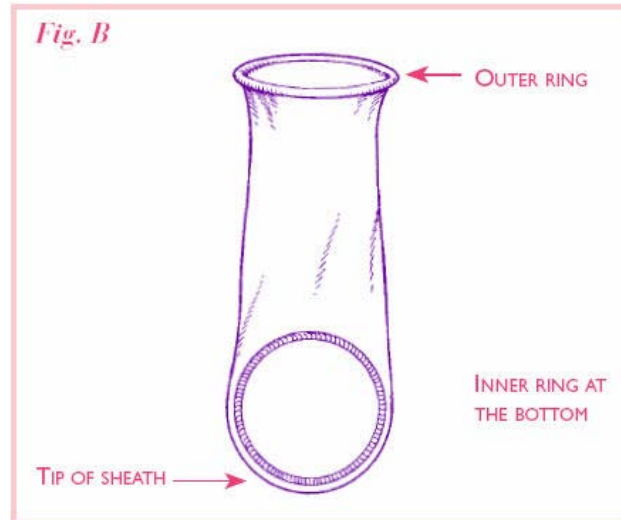
The FC2 Female Condom - General Information

The Look



What is FC2 Female Condom®?

- FC2 is a strong, soft, nitrile sheath or pouch 17 cm (6.5 inches-the same as the male condom) in length... Nitrile polymer (non-latex), is thin and strong, and heats to body temperature
- FC2 is worn by the woman during sex and placed up by the pubic bone
- FC2 can be inserted prior to sex since it is worn by the woman and the man does not need to be erect
- FC2 **cannot** be used at the same time as a male condom
- FC2 contains a silicone-based lubricant on the inside of the condom, but additional lubrication can be used. FC2 does not contain spermicide.



How FC2 Works

- FC2 has a flexible ring at the closed end of the pouch with a slightly larger ring at the open end.
- At the closed end of the sheath, the flexible ring is inserted into the vagina to hold the female condom in place.
- At the open end of the sheath, the ring stays outside the vulva at the entrance to the vagina. This ring acts as a guide during penis penetration and it also prevents the sheath from bunching up inside the vagina.

Why FC2 is important?

- Female condoms work to prevent pregnancy and STIs, including HIV, by lining the inside of the vagina, preventing skin touching skin.
- They collect pre-cum and semen when a man ejaculates, keeping sperm from entering the vagina and thereby preventing pregnancy and reducing the risk of STIs.
- Women have options available to them to increase protected sex acts and decrease the transmission of STIs and unintended pregnancy. Providers play an important role in presenting all the options of protection to their clients.

Who Can Use FC2?

- Women who are concerned about unintended pregnancy and STIs.
- Women who are menstruating.
- Women who have recently given birth.
- Women who have a retroverted uterus.
- Women who have had a hysterectomy.
- Women who are peri and postmenopausal.
- Women who are allergic/sensitive to latex.

How Effective is FC2?

Studies show the clinical effectiveness of FC2 is equivalent or comparable to FC1. Over 16 years of studies have shown the female condom is an effective barrier against many common STIs, including HIV.

- It is estimated that correct and consistent use of the female condom for one year with an HIV+ partner could reduce a woman's risk of acquiring HIV by 90%.
- Studies in the U.S. and internationally have found that the prevalence of STIs decline and the rate of protected sex acts increase when female condoms are made available alongside the male condom.

FC1	FC2
Made of polyurethane	Made of Nitrile polymer
Has a seam	No seam
Outer ring is polyurethane	Outer ring is rolled Nitrile polymer
Same design	
Same dimensions	
Same method of insertion	
Same safety and efficacy	
Same acceptability	

FC2 Female Condom

Understanding the Female Anatomy

External Female Anatomy

Major external anatomy points, as they relate to FC2 include:

The Labia

- Also known as the "lips," the labia comprises the inner and outer lips of the vulva.
- **The lips are spread when inserting FC2.**

The Clitoris

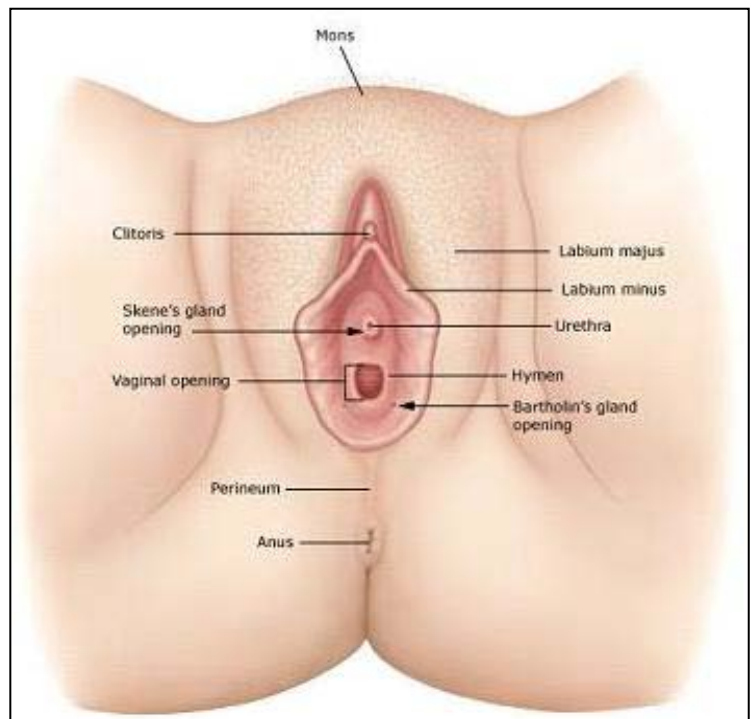
- This small body of smooth spongy tissue is highly sexually sensitive, containing around 8,000 nerve endings tightly packed together. During sexual excitement, the clitoris may become erect and the hood will retract to make the clitoris more accessible.
- **FC2 may provide clitoral stimulation** during use as the outer ring sometimes rubs against the clitoris.

The Urethra

- Show the urethra, explaining that inserting FC2 will not interfere with normal bodily functions such as urination.

The Vaginal Opening

- Show the vaginal opening, explaining that **this is where FC2 is inserted** and is also where the penis enters during sexual intercourse.

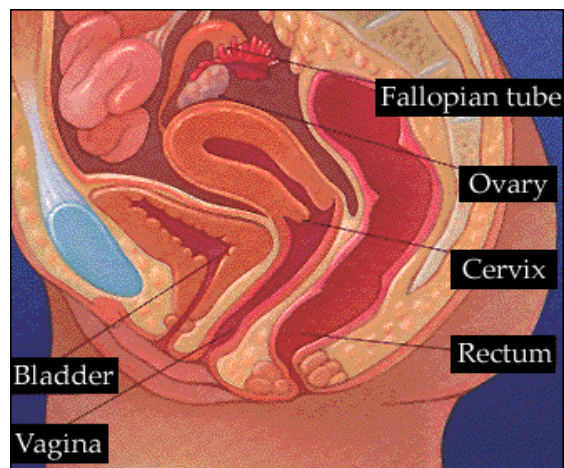


Internal Female Anatomy

Major internal anatomy points, as they relate to FC2 include:

The Vaginal Canal

- The vagina is a pouch that forms the vaginal canal.
- It extends from the vaginal opening to the cervix, (the opening to the uterus).
- The penis is inserted into the vaginal canal during sexual intercourse; the vagina is also the birth canal through which the baby passes during child birth.
- The average vaginal canal is three inches long, possibly four in women who have given birth.
- **FC2 lines the vaginal canal and adheres to the vaginal walls.**



The Cervix

- The cervix is the lower, narrow part of the uterus (womb).
- The cervix opens into the vagina, which leads to the outside of the body.
- When inserted properly FC2 covers the cervix.

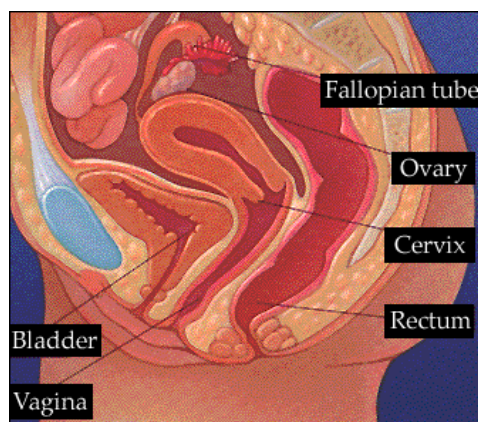
Pubic Bone

- The pubic bone is the front bottom of the three principal bones composing either half of the pelvis.
- The inner ring of FC2 goes behind the pubic bone, anchoring it into place.

Note: Sometimes when using FC2 the woman may complain that it doesn't feel right or is uncomfortable. Typically, this feeling is the direct result of the woman experiencing one or two insertion errors.

- The first potential problem: Instead of the inner ring resting against the cervix the inner ring is rubbing or hitting against the cervix and all the woman needs to do is insert her finger and adjust the inner ring.
- The second potential problem: The inner ring is not snugly behind the pubic bone. All the woman needs to do is simply re-insert, being sure to pop the inner ring behind the pubic bone.

Remember- Pop behind the pubic bone and/or adjust the inner ring.



FC2 Female Condom and Proper Use

Preparing for Use

The following steps provide a useful guide for preparing to insert the female condom:

- Start with one FC2 package.
- As with the male condom, it is important to check the expiration date prior to opening FC2.

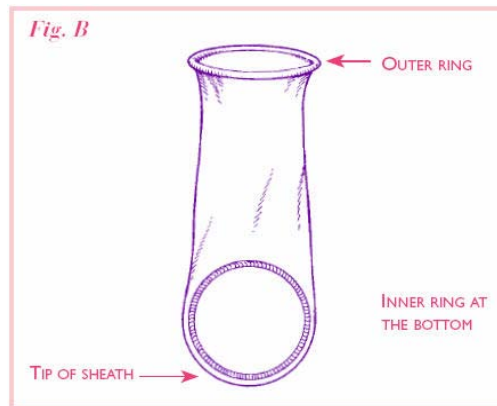
To Open The Packet:

- Locate arrow at tear notch on upper right-hand corner and tear open Fig. A.
- Rub the outside of the pouch together to be sure the lubrication is evenly spread inside the pouch from the bottom to the top.
- Take out FC2 and look at it closely to make sure it is not damaged.

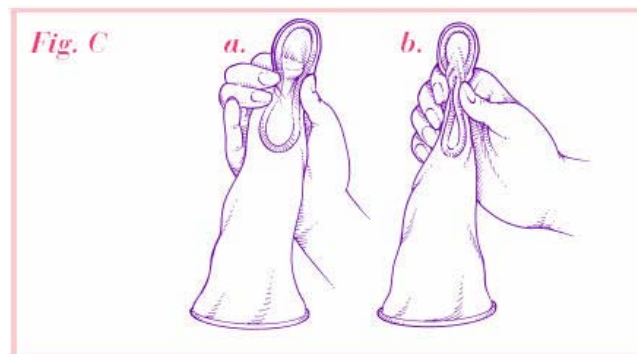


To Insert the FC2 Female Condom:

- Find a comfortable position. Try standing with one foot up on a chair, or sit with knees apart, or squat down.
- Be sure the inner ring is at the bottom, closed-end of the pouch Fig. B.

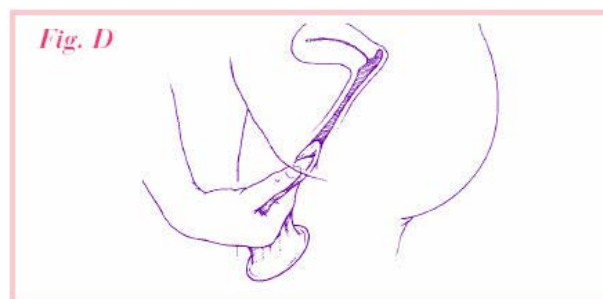


- Hold the pouch with the open end hanging down. While holding the outside of the pouch, squeeze the inner ring with your thumb and middle finger.
- Place your index finger between the thumb and middle finger and keep squeezing the inner ring Fig. C (a).
- Or just squeeze - whichever is easier for you Fig. C (b).

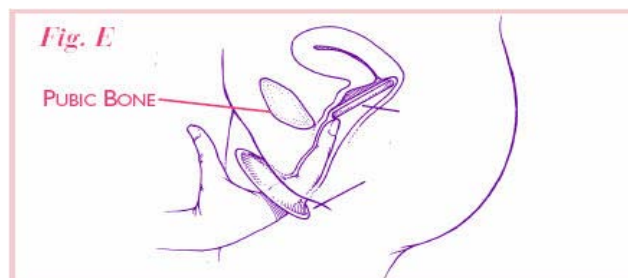


To Insert the FC2 Female Condom, cont'd:

- Still squeezing the FC2 Female Condom with your other hand, spread the lips of the vagina as if you were getting ready to insert a tampon.
- Insert the squeezed FC2 Female Condom as shown in Fig. D.
- Take your time. If the FC2 Female Condom is slippery to insert, let it go and start over.

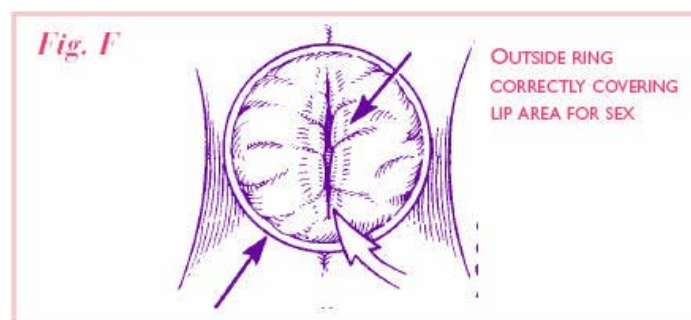


- Now push the inner ring and the pouch the rest of the way up into the vagina with your index finger. Check to be sure the inner ring is up just past your pubic bone Fig. E.
- You will feel your pubic bone by curving your index finger when it is a couple of inches inside the vagina.
- This step may be hard to do on the first or second try because the FC2 Female Condom is lubricated.
- Take your time and push the closed end of the FC2 Female Condom up to where you can feel the pubic bone.



To Insert the FC2 Female Condom, cont'd:

- Make sure the FC2 Female Condom is inserted straight (not twisted) into the vagina.
- It is also important that the outside ring lies against the outer lips of the vagina as shown in Fig. F.
- About one inch of the open end will stay outside your body. FIG. F. While this may look unusual, this part of the FC2 Female Condom helps protect you and your partner during sex. Once the penis enters, the vagina will expand and the slack will decrease.

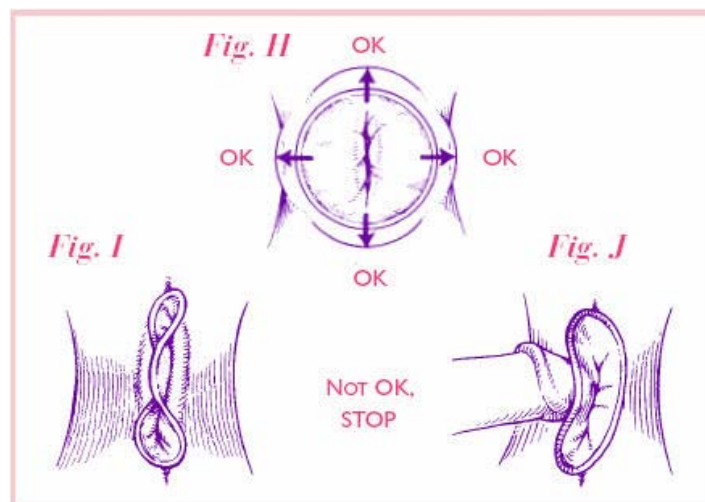


- Until you and your partner become comfortable using the FC2 Female Condom, use your hand to guide the penis into the vagina. See Fig. G.
- After two or three times, you should become familiar with using the FC2 Female Condom and should hardly notice the pouch or the outer ring during sex.



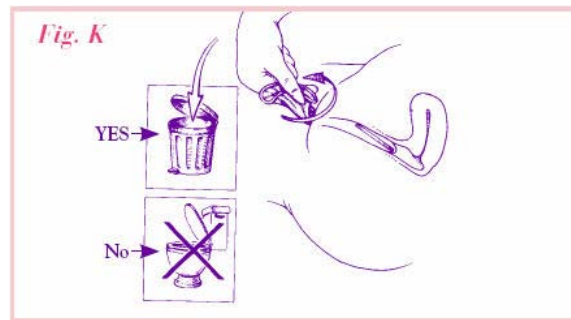
During Intercourse

- You may notice that the FC2 Female Condom moves around during sex. See Fig. H.
- Movement side-to-side of the outer ring is normal.
- Sometimes the FC2 Female Condom may slip up and down in the vagina, "riding" on the penis. Both the vagina and the penis are still covered.
- However, if you notice the FC2 Female Condom is slipping out of the vagina, STOP, remove, and insert a new FC2 Female Condom.
- If you begin to feel the outer ring being pushed into the vagina, STOP (Fig. I). Or, if the penis starts to enter underneath or beside the pouch, STOP (Fig. J). Take out the FC2 Female Condom. Put in a new FC2 Female Condom. Make sure the outside part lies over vagina.



After Intercourse

- To take out the FC2 Female Condom, squeeze and twist the outer ring to keep the sperm inside the pouch. Pull out gently. Throw away in a trash can. Do not flush. Do not reuse. Please see Fig. K.



FC2 Female Condom - Not Your Typical Condom

The following chart outlines some of the difference and benefits of FC2 when compared to the male condom.

Comparison Between a Male and FC2 Female Condom	
Latex Male Condom	FC2 Female Condom
Rolled on the man's penis	Inserted into the woman's vagina
Made from latex	Made from synthetic rubber
Fits on the penis	Loosely lines the vagina
Can only be put on an erect penis	Can be inserted prior to intercourse - not dependent on an erection
Must be removed immediately after ejaculation	Does not need to be removed immediately after ejaculation but should be removed before the woman gets up
Covers most of the penis and protects the woman's internal genitalia	Covers both the woman's internal and external genitalia and the base of the penis, thus provides greater protection
Little lubrication	Highly lubricated, helps during insertion and intercourse
Should only be used with water based lubricants	Can be used with oil or water based lubricants

FC2 Female Condom

Tips for Communicating with your partner about sex

The timing, place, knowing what you want to say and how you say it are key to effective negotiation. Know what to say and do should the outcome be negative such as aggression or violence.

- Choose a relaxing environment in a neutral location, preferably outside the bedroom, where neither of you feel pressured.
- Do not wait until you or your partner is sexually aroused to discuss safer sex. In the heat of the moment, you and your partner may be unable to talk effectively.
- Use "I" statements when talking. For example, "I would feel more comfortable if we used a condom".
- Be a good listener. Let your partner know that you hear, understand, and care about what she/he is saying and feeling.
- Be "ask-able" - let your partner know that you are open to questions and that you won't jump on him/her or be off ended by questions.
- Be patient and remain firm in your decision that talking is important.
- Recognize your limits. You don't have to know all the answers.
- Understand that success in talking does not mean one person getting the other person to do something. It means that you have both said what you think and feel respectfully and honestly.
- Avoid making assumptions. Ask open-ended questions to discuss expectations, past and present sexual relationships, contraceptive use, HIV testing, etc. For example, "What do you think about us both going for an HIV test?"
- Ask questions to clarify what you believe you heard. For example, "I think you said you want us to use condoms. Is that right?"
- Avoid judging, labeling, blaming, threatening, bribing or manipulating your partner.
- Don't let your partner judge, label, threaten, coerce or bribe you.

FC2 Female Condom - Condom Comebacks

When Your Partner Says...	You Can Say...
"It kills the mood"	"It puts me in the mood and you can put it in for me"
"You won't catch anything from me"	"It is really sexy when I know you care about me and that you do not want me to get pregnant"
"It takes too long"	"You'll be turning me on every second as you watch me to put it in..."
"It doesn't feel good"	"This is different, it conforms to me and it warms to body temperature so it feels more natural"
"I don't want to wear that - it looks weird!"	"It is something new and we can make it fun, you can help me put it in or watch me"
"We have been having sex without condoms"	"I will be a lot more relaxed and enjoy myself more if I don't have to worry about getting pregnant."
"I don't use condoms"	"If you do not wear a condom or you do not want me to wear a condom then I am not having sex"
"I will find someone who doesn't care if I wear a condom"	"Then you really do not care about me anyway so go right ahead"
"Condoms break too often."	"FC2 is nitrile and is strong."

*Adapted from Talking About Sex, Duke University Student Health Center,
http://healthydevil.studentaffairs.duke.edu/health_info/Communication%20Talking%20About%20Sex.html

Why Should You Try FC2 Female Condom?

- FC2 can increase a woman's sense of empowerment as she is taking the initiative to protect herself and her partner.
- FC2 increases sexual stimulation because the material is very thin and warms to body temperature.
- External ring rubs against clitoris and increases pleasure for many women.
- Men do not have to have/ maintain an erection to use FC2. FC2 is a good option for men who are unable to maintain an erection with the male condom.
- Men do not have to withdraw right after ejaculation, which may lead to more intimacy when using FC2.
- FC2 can be inserted ahead of time so there are no interruptions to "spoil the mood".
- Insertion of FC2 can be incorporated into sexual play, the partner can watch as it is put in place OR can help insert it.
- FC2 is a great choice for people with sensitivities to latex.
- FC2 can be used with any kind of lubricant (water or oil-based lubricants).
- FC2 provides an option for those times when a couple does not want to use the male condom (NOTE: Never use a male condom and FC2 at the same time).
- FC2 is not tight or constricting around the penis; some men prefer FC2 to the male condom.
- The inner ring of FC2 can stimulate the tip of the penis during intercourse.
- The man does not have to worry about wearing a condom.
- FC2 provides effective dual protection, reducing the worry during sex about pregnancy and STIs/HIV.

Glossary

The following words are defined for your easy reference. The words are defined within the context of the promotion of FC2.

AIDS - Acquired immunodeficiency syndrome, a human viral disease that ravages the immune system, undermining the body's ability to defend itself from infection and disease.

Anatomy - the human body and all of its parts and systems.

Attitudes - how we act, carry ourselves, feel, and function based on our values and beliefs.

Biological Risk - something about the make-up of our anatomy that increases our chances of contracting an illness or in this case sexually transmitted disease (STI) including HIV.

Cervix - This part of the female anatomy is on the outside and is part of the vulva. The cervix opens into the vagina, which leads to the inside of the body. When inserted properly FC2 covers the cervix.

Clitoris - This small body of smooth spongy tissue is highly sexually sensitive, containing around 8,000 nerve endings tightly packed together. During sexual excitement, the clitoris may become erect and the hood will retract to make the clitoris more accessible.

Dual protection - when a medically approved product provides protection against both unintended pregnancy and sexually transmitted infections (STIs), including HIV/AIDS. FC2 provide dual protection.

Effective (Efficacy) - the ability for a product to achieve its desired effect. When used correctly, the FC2 has been clinically proven to be effective in protecting sexual partners from unintended pregnancy and STIs, including HIV.

Empower- to give power or authority to. The FC2 empowers women to have more power and authority over the protected sex options.

FC1 - Female Condom 1. First generation female condom. The FC1 is out of distribution and is no longer manufactured.

FC2 - Female Condom 2. Second generation female condom.

Female Health Company - The Female Health Company ("FHC" or the "Company") manufactures markets and sells the FC2 female condom, the only currently available product under a woman's control that is approved by the U.S. Food and Drug Administration (FDA). FHC is based in Chicago, Illinois.

Food and Drug Administration (FDA) - The Food and Drug Administration (FDA) is a regulatory agency in the United States which is responsible for ensuring the safety of an array of consumer products, including medical devices such as FC2. The FDA is within the Department of Health and Human Services.

Heterosexual - In this context, FC2 studies have been performed by the FDA and other research institutions to test the efficacy of the FC2 within one specific heterosexual sex act; penis inserted into the vagina.

Hinder - Not helpful. Slows progress. In this case, when providers share or show their biases or negative attitudes and beliefs about FC2 and its use with client, clients are less likely to try FC2.

HIV (Human Immunodeficiency Virus) - is the virus that causes AIDS. HIV is transmitted through blood, semen, vaginal fluid, and breast milk. HIV CAN be prevented and is NOT transmitted through casual contact (hugging, sharing an apartment, playing basketball, etc.).

Insertion - to put in.

Intercourse - in this context, the insertion of the penis into the vagina.

Launched (launching) - to introduce to the public or to a market. In this context, the FC2 is currently being launched or introduced to the U.S. market, with your help.

Lubricant (Lubrication, Lubricated) - a moist substance that comes on condoms, it makes the condom moist to increase sexual pleasure and to decrease condom breakage. Latex condoms can only be used with water based lubricants, such as KY, Astroglide, etc. FC2, made of nitrile, can be used with oil-based or water-based lubricant.

Male Condom - A thin sheath worn over the penis during sexual intercourse. When used correctly and consistently, condoms made of latex or polyurethane protect against pregnancy and sexually transmitted infections, including HIV.

Menstruation - The monthly discharge of blood and tissue from the lining of the uterus.

Milestones - important dates to note and remember in the history of a person or product's life.

Myths - not true. False.

Negotiate - The process of negotiation involves at least two people with two different views on an issue, in this case, sexual behavior. Each person tries to persuade the other person to support his/her view, or at least to agree on a compromise or middle position. In this situation the goal is safer sex.

No identified risk - When a newly diagnosed woman can't identify her male partner's HIV status or "high-risk" behavior (e.g. male to male sexual contact or injection drug use), and other means of transmission are ruled out, the CDC surveillance system automatically places her in a generic category labeled "no identified risk" (NIR).

Non-lubricated - no lubricant (see definition above) included.

Pelvic Model - a somewhat life-like teaching tool (made of soft plastic or silicone) that generally displays the external genitalia of a woman and the vaginal opening.

Penetration - in this context inserting the penis into the vagina.

Penis Model - a somewhat life-like teaching tool (made of wood, plastic, or silicone) that displays an erect penis and sometimes scrotal sac.

Physiology - the functions of biological part. In this context it is the workings of the female anatomy. How the female anatomy functions, what it does.

Promotion (Promotional Messages) - a specific marketing approach and messages developed by a company in order to make sure the public is receiving the most accurate and appealing information and facts about a product.

Provider - someone that provides services to the community. For example, outreach worker, nurse, health educators, etc.

Scientific Dossier - A collection of papers giving detailed information about a particular person or subject. In this context, it involves all the information provided to FDA and other agencies about FC2.

Sexual intercourse - a variety of sexual or intimate contact, including vaginal, anal, and oral genital intercourse. Usually in this context, it is referring to vaginal sex.

Sexually Transmitted Infections (STIs) - infections that are transmitted through sexual contact: anal, vaginal, or oral. STIs are generally divided into two categories, bacterial (i.e. gonorrhea, Chlamydia, and syphilis) and viral (i.e. genital warts, herpes, Hepatitis, and HIV). Bacterial infections can be cured if detected early. Although new strains of antibiotic resistant bacterial STIS are emerging. Viral infections are incurable but the symptoms are controllable if detected early.

Sexual/Reproductive Health - According to the UN, "Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters related to the reproductive system and to its functions and processes."

Sexual Pleasure - when sexual intercourse feels good.

Sperm - Male reproductive cells that can unite with (fertilize) a female's egg, leading to pregnancy.

Transmission - to pass from person to person

United Nations Population Fund (UNFPA) - An international, trusted source on content in health and wellness worldwide.

United States Agency for International Development (USAID) - a U.S. government agency that provides humanitarian aid and assistance for development to other countries.

Unintended Pregnancy - a pregnancy that was not planned for.

Vagina - The passage that goes from the cervix to the outside of the female body. The penis is inserted into the vaginal canal during sexual intercourse; the vagina is also the birth canal through which the baby passes during child birth. FC2 lines the vaginal canal and adheres to the vaginal walls.

Values - enduring, important beliefs held by an individual, family, community or culture.

World Health Organization (WHO) - a United Nations agency to coordinate international health activities and to help governments improve health services.

A full bibliography can be found at our website at

www.fc2.us.com/healthprofessionals/resources.html

This leaflet explains how to use the **FC2 FEMALE CONDOM** and answers some questions women often ask about its use. Please read this leaflet carefully before you use the **FC2 FEMALE CONDOM** for the first time.



The **FC2 FEMALE CONDOM** is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs).

IMPORTANT INFORMATION

- Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including HIV/AIDS, if used correctly.
- If you are not going to use a male natural rubber latex condom, you can use the FC2 Female Condom to help protect yourself and your partner.
- The FC2 Female Condom only works every time you use it. Use it correctly every time you have sex.
- Before you try the FC2 Female Condom, be sure to read the directions and learn how to use it correctly.

Manufactured by:
The Female Health Company
Chicago IL / London UK / Malaysia
515 North State Street, Suite 2225
Chicago, IL 60654
www.femalehealth.com
This product protected by
U.S. Patent Pending & others.
Date: March 2010

READ THIS BEFORE USING THE FC2 FEMALE CONDOM
The FC2 Female Condom is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs).
If you are being treated for a sexually transmitted infection (STI) or think you have one, see your healthcare provider.

IMPORTANT THINGS TO KNOW

- Important things to note for the best protection with the FC2 Female Condom**
 - Before you try the FC2 be sure to read the directions and learn how to use it correctly. Practice putting the FC2 in the vagina without having sex to get familiar with how it works.
 - Make sure the FC2 is in place before the penis enters.
 - No studies have been conducted to demonstrate if a spermicide is compatible with FC2 material or if using a spermicide increases the FC2's effectiveness.
 - Store the FC2 at normal room temperature.
 - The following are problems that have been reported when using the FC2 during sex:
 - the penis can push the FC2 condom (including outer ring) inside the vagina;
 - the penis slips to the side of the FC2 during intercourse and enters the vagina without FC2 protection;
 - the FC2 female condom breaks during use; and
 - the FC2 slips completely out of the vagina.
 - In each of the scenarios described above, the risk of vaginal exposure to semen is increased. If any of these occur, you should dispose of that female condom and use a new one.

USING THE FC2

- The FC2 Female Condom is inserted before sex. Most women insert the FC2 Female Condom between 2 to 20 minutes before sex.
- The FC2 Female Condom should be removed after sex and before you stand up. It is for one-time use.

BENEFITS OF USING THE FC2

- Using the FC2 during sexual intercourse can help protect against getting a sexually transmitted infection or getting pregnant.
- The FC2 does not contain natural rubber latex.
- The FC2 provides women with an option for protection which they can initiate.
- Women can insert the FC2 ahead of the sex act. This allows for a more spontaneous act because an erection is not needed to insert the FC2.

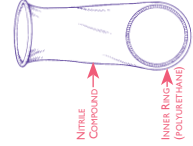
RISKS OF USING THE FC2

- Use of the FC2 Female Condom correctly every time you have sex, if the FC2 is not used correctly every time, your risk of getting a sexually transmitted infection or becoming pregnant will be higher.
- Incorrect use may result in the FC2 not providing protection. To avoid risk of incorrect use, read the instructions carefully prior to use.
- Research has shown that the following events are rare but can occur when using the FC2:
 - discomfort during insertion
 - discomfort during infection
 - discomfort during sex
 - burning sensation, rash or itching.

SOME FEATURES OF USING THE FC2
You can insert the FC2 Female Condom yourself. It gives you a way to protect yourself.
The FC2 Female Condom warms up as soon as you insert it. It is both strong and soft.

DESCRIPTION

The FC2 Female Condom is a soft, loose-fitting sheath. It has a ring at each end. The inner ring at the closed end is made of polyurethane and is used to help insert the FC2 Female Condom inside the vagina and helps to hold it in place. It is not connected to the female condom. The outer rim of the sheath, on the open end stays outside the vagina. The FC2 Female Condom comes pre-lubricated with silicone.



ABOUT THE FC2'S EFFECTIVENESS

The effectiveness of the FC2 Female Condom is based on a study conducted in South Africa comparing the FC2 Female Condom to the earlier version FCI Female Condom. This comparative study evaluated the FC2 and FCI with respect to the four possible problems described earlier in the labeling:

- The female condom may break during use;
- The female condom may slip out of the vagina during use;
- The penis may push the female condom into the vagina; and
- The penis may push past the condom into the vagina (unprotected).

These four problems are the only ways that the vagina would be exposed to semen when using the FC2 Female Condom and this comparative study showed that the rates of these problems with the FCI and FC2 female condoms are similar. Although the FC2 and FCI female condoms are similar, although the FC2 was not studied for contraception or STI protection, the FC2 effectiveness can be inferred on the basis of this comparative study and an earlier study that demonstrated the effectiveness of the FCI for contraception. These results are given in the table below.

Below is information on how well different contraceptives protect you against pregnancy. The numbers are based upon typical use and perfect use. Typical use rates indicate that the method may have been used incorrectly, may not have been used with every sex act, or may have failed during use. Perfect use rates indicate that the method was used correctly with every sex act but failed anyway.

CONTRACEPTION METHOD	% OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY WITHIN THE FIRST YEAR OF USE	
	TYPICAL USE	PERFECT USE
No method	85	85
Spermicides	29	18
Withdrawal	27	+
Typical use rates based on method	25	+
Barrier Methods		
Condoms	16	0
Diaphragm + Spermicide	32	20
Female Condom	16	6
Male Condom	21	5
Female Condom	15	2
Hormonal Methods		
Combined pill and progesterin-only pill	8	0.3
Injectable	8	0.3
Implant	8	0.3
Depot-Provera®	3	0.3
Levonelle®	0.05	0.05
UD-IUD (Gard® (copper I))	0.8	0.2
Mirena® (LNG-IUS)	0.2	0.2
Female Sterilization	0.5	0.5
Male Sterilization	0.15	0.10

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%. **Method:** LAM is a highly effective, temporary method of contraception.

Source: Trussardi, Contraceptive Efficacy. In: Hatcher RA, Trussardi J, Nelson AL, Cramer DW, et al. *Contraceptive Technology*. 10th Edition. New York, NY: Arden Media; 2007. www.contraceptivetechnology.org
 *The numbers are based on the assumptions of the Reality Check program. The numbers do not include the risk of pregnancy from the use of the method in the first year of use among South African women. Contraception. 2006 Apr; 71(4):384-93.

HOW TO USE THE FC2 FEMALE CONDOM

TO OPEN THE PACKET
1. Locate the arrow at right-hand corner and tear open (Fig. A).
2. Rub the outside of the pouch together to be sure the lubrication is evenly spread inside the pouch from the bottom to the top.
3. Take out the FC2 and look at it closely to make sure it is not damaged.



TO INSERT THE FC2 FEMALE CONDOM
4. Find a comfortable position. Try standing with one foot up on a chair, or sit with knees apart, or squat down.
5. Be sure the inner ring is at the bottom, closed-end of the pouch (Fig. B).
6. Hold the pouch with the open end hanging down. While holding the outside of the pouch, squeeze the inner ring with your thumb and middle finger.
7. Place your index finger between the thumb and middle finger and keep squeezing the inner ring (Fig. C (a)).
8. Or just squeeze—which ever is easier for you (Fig. C (b)).
9. Your other hand, spread the lips of the vagina as if you were getting ready to insert a tampon.



DURING INTERCOURSE
10. You may notice that the FC2 Female Condom moves around during sex. See Fig. H.
11. After two or three times, you should become familiar with using the FC2 Female Condom and should hardly notice the pouch or the outer ring during sex.
12. Movement side-to-side of the outer ring is normal.
13. Sometimes the FC2 Female Condom may slip up and down in the vagina, "riding" on the penis. Both the vagina and the penis are still covered.
14. However, if you notice the FC2 Female Condom is slipping out of the vagina, STOP, remove, and insert a new FC2 Female Condom.
15. If you begin to feel the outer ring being pushed into the vagina, STOP (Fig. I). Or, if the penis starts to enter underneath or beside the pouch, STOP (Fig. J). Take out the FC2 Female Condom. Put in a new FC2 Female Condom. Make sure the outside part lies over vagina.



AFTER INTERCOURSE
16. To take out the FC2 Female Condom, squeeze and twist the outer ring to keep the sperm inside the pouch. Pull out gently. Throw away in a trash can. Do not flush. Do not reuse. Please see Fig. K.
17. To help reduce your risk of pregnancy and the spreading of a sexually transmitted infection:

- Use a new FC2 Female Condom correctly every time you have sex.
- Follow the directions carefully.
- Be sure you don't tear the FC2, with fingernails or other sharp objects.



QUESTIONS YOU MAY HAVE ABOUT THE CORRECT USE OF THE FC2 FEMALE CONDOM
Will the FC2 Female Condom always protect against pregnancy and STIs?
No method is 100 percent effective. Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including AIDS (HIV infection), if used correctly. If you are not going to use a male condom, you can use the FC2 to help protect yourself and your partner.

How do I know when the FC2 Female Condom is up far enough?
Using your index finger, push the device so that the lower ring of the device is against the pubic bone. You will find when it is a couple of inches inside the vagina.

What do I do if the outer ring is pushed inside the vagina?
STOP. Remove the FC2 Female Condom device. Insert a new FC2 Female Condom according to the directions.

Will I feel the FC2 Female Condom once it is in place?
Yes, it is possible that you will be aware of it.

What do I do if the penis is inserted outside the female condom?
You should ask your partner to withdraw the penis and help him reinsert the penis inside the condom.

Will I feel the FC2 Female Condom or hear while I am using it?
Studies show that the FC2 Female Condom rips or tears less than 1% of the time. If you think the FC2 Female Condom has been ripped or torn, remove it right away, throw it away, and insert a new FC2 Female Condom.

Will the FC2 Female Condom bunch up inside the vagina?
The FC2 Female Condom should not bunch up inside if it is inserted correctly. If you feel the outer ring begin to slip inside, STOP. Remove the FC2 Female Condom device. Insert a new FC2 Female Condom device according to the directions.

What does the outer ring feel like during sex?
While aware of the outer ring, most women say that it does not interfere with intercourse.

What do I do if the FC2 Female Condom does not stay in place during sex?
If the FC2 Female Condom moves down the vagina causing discomfort, either push it back up or remove the FC2 Female Condom. If you remove the FC2 Female Condom, use a new one.

DO YOU HAVE A QUESTION ON HOW TO USE THE FC2 FEMALE CONDOM?
Call your healthcare provider or call 1-800-274-6601

El presente folleto explica el modo de uso del CONDÓN FEMENINO **fc2** e incluye respuestas a algunas preguntas que las mujeres a menudo se hacen respecto de su uso. Lea el presente folleto atentamente antes de usar el CONDÓN FEMENINO **fc2** por primera vez.



INFORMACIÓN IMPORTANTE

- Los condones de látex de caucho natural para hombres son altamente efectivos en la prevención de infecciones de transmisión sexual, incluido el VIH/SIDA, de ser usados correctamente.
- Si usted no va a utilizar un condón de látex de caucho natural masculino, puede usar el Condón Femenino FC2 para protegerse usted y proteger a su pareja.
- El Condón Femenino FC2 solo funciona cuando se lo utiliza. Utilícelo de manera correcta cada vez que tenga relaciones sexuales.
- Antes de probar el Condón Femenino FC2, asegúrese de leer las instrucciones y aprenda a utilizarlo correctamente.

Fabricado por:
The Female Health Company
Chicago, IL / Londres Reino Unido / Malasia

515 North State Street, Suite 2225
Chicago, IL 60654
www.femalehealth.com

Este producto está protegido por una Patente estadounidense en trámite y otros.

Fecha: marzo de 2010

LEA LA SIGUIENTE INFORMACIÓN ANTES DE UTILIZAR EL CONDÓN FEMENINO **fc2**

Se recomienda el uso del CONDÓN FEMENINO FC2 para la prevención del embarazo, el VIH/SIDA y otras infecciones de transmisión sexual (ITS). Si se encuentra en tratamiento por una infección de transmisión sexual (ITS) o cree que puede padecer de una, consulte a su proveedor de salud.

PUNTOS IMPORTANTES PARA TENER EN CUENTA

- Puntos importantes para tener en cuenta para la mejor protección con el Condón Femenino FC2
- 1 Antes de probar el Condón Femenino FC2, asegúrese de leer las instrucciones y aprenda a utilizarlo correctamente.
 - 2 Practique colocar el FC2 dentro de la vagina sin tener sexo para familiarizarse con el modo de uso.
 - 3 Asegúrese de que el FC2 esté en su lugar antes del ingreso del pene.
 - 4 Ninguno de los estudios realizados demostraron si los espermicidas son compatibles con el material del FC2 o si el uso de un espermicida aumenta la eficacia del FC2.
 - 5 Conserve el FC2 a temperatura ambiente.
 - 6 A continuación se incluyen algunos problemas que se han registrado al utilizar el FC2 durante la relación sexual:
 - El pene puede empujar el condón FC2 (incluido el anillo exterior) adentro de la vagina.
 - El pene se desliza hacia el lateral del FC2 durante la relación sexual e ingresa adentro de la vagina sin la protección del FC2.
 - El condón femenino FC2 se rompe durante el uso.
 - El FC2 se desliza completamente fuera de la vagina.

UTILICE FC2

- El Condón Femenino FC2 se inserta antes de la relación sexual. La mayoría de las mujeres insertan el Condón Femenino FC2 entre 2 a 20 minutos antes de esta.
- El Condón Femenino FC2 debe retirarse luego del acto sexual, y antes de ponerse de pie. Sólo puede utilizarse una vez.

BENEFICIOS DE LA UTILIZACIÓN DEL FC2

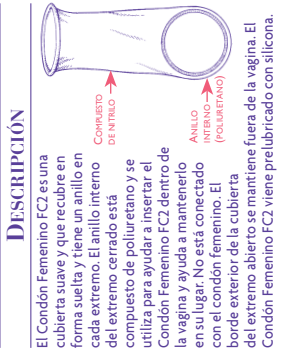
- El uso del FC2 durante la relación sexual puede colaborar en la protección contra las infecciones de transmisión sexual o a evitar el embarazo.
- El FC2 no contiene látex de caucho natural.
- El FC2 ofrece a las mujeres una opción para protegerse que ellas pueden iniciar.
- Las mujeres pueden insertar el FC2 antes del acto sexual. Esto permite que el acto sea más espontáneo, dado que no es necesaria la erección para insertar el FC2.

LOS PELIGROS DE UTILIZAR EL FC2

- Utilice el Condón Femenino FC2 correctamente cada vez que tenga relaciones sexuales. Si el FC2 no se usa del modo correcto, el riesgo de contraer infecciones de transmisión sexual o de quedar embarazada se incrementará.
- El uso incorrecto podría ocasionar que el FC2 no ofrezca protección alguna. Para evitar el riesgo de uso incorrecto, lea las instrucciones atentamente antes de usarlo.
- Las investigaciones demuestran que los siguientes hechos son raros pero pueden ocurrir al utilizar el FC2:
 - incomodidad durante la inserción
 - dolor luego de la inserción, antes de la relación sexual
 - incomodidad durante la relación sexual
 - sensación de ardo, supulido o comezón.

ALGUNAS CARACTERÍSTICAS DE USAR EL CONDÓN DE LA HEMBRA FC2

- Usted misma puede colocarse el Condón Femenino FC2. Esto le ofrece la oportunidad de protegerse por sí sola.
- El Condón Femenino FC2 se calentará apenas lo inserte. Es fuerte y suave.



SOBRE LA EFECTIVIDAD DEL FC2

La efectividad del Condón Femenino FC2 se basa en un estudio realizado en Sudáfrica en el que se comparó el Condón Femenino FC2 con una versión anterior, el Condón Femenino FC1. Este estudio comparativo analizó el FC2 y el FC1 respecto de otros cuatro posibles problemas descriptos anteriormente en el artículo:

- El condón femenino puede romperse durante el uso;
- El condón femenino podría deslizarse fuera de la vagina durante el uso;
- El pene podría empujar el condón femenino adentro de la vagina;
- El pene podría empujar el condón hacia adentro de la vagina (sin protección).

 Los datos de este estudio demuestran que las cifras de estos problemas en los condones Femeninos FC1 y FC2 son similares. Aunque el FC2 no fue estudiado en cuanto a su anticoncepción ni a la protección frente a las ITS, la efectividad del FC2 puede inferirse sobre la base de este estudio comparativo y un estudio anterior que demuestra la efectividad del FC1 para anticoncepción en la siguiente tabla.

% DE MUJERES QUE EXPERIMENTARON UN EMBARAZO NO BUSCADO DENTRO DEL PRIMER AÑO DE USO

MÉTODO ANTICONCEPTIVO	Uso Habitual	Parecido
Ningún método	35	35
Anticoncepción hormonal	27	4
Métodos basados en la contracepción sobre Fertilidad	27	4
Capitación cervical	25	-
Condón femenino FC1	21	5
Condón femenino FC2	15	5
Diaphragma + espermicida	16	0
Barreras previas	32	20
Condón	16	6

MÉTODOS HORMONALES

Método	Uso Habitual	Parecido
Píldoras combinadas y píldoras solo a base de progestina	8	0.3
Evra Patch®	3	0.3
Depo-Provera®	3	0.3
Implantón®	0.05	0.05

Método de amonora de la lactancia: el MEA es un método anticonceptivo altamente efectivo y temporal.

Estérilización: la esterilización femenina tiene una efectividad del 99.8% y la masculina del 98.3%.

Píldoras anticoncepcionales de emergencia: el tratamiento iniciado dentro de las 72 horas posteriores a la relación sexual sin protección disminuye el riesgo de embarazo por lo menos en un 78%.

Método de amonora de la lactancia: el MEA es un método anticonceptivo altamente efectivo y temporal.

Fuente: Trussell J, Coombs RW, Richter BA, Trussell AL, Nelson AL, et al. *Contraception*. 2002;65:1033-1047.
1. Redferns M, Bekink A, et al. *Performance of the Realiy polyurethane female condom*. 2006;44(4):385-390.
2. *South African women's contraceptive use, 2006*. Apr. 21(4):385-390.

POSIBLES PRECUNTAS SOBRE EL USO CORRECTO DEL CONDÓN FEMENINO FC2

P. ¿El Condón Femenino FC2 siempre ofrece protección contra el embarazo y las ITS?

R. Ningún método es cien por ciento efectivo. Los condones de látex de caucho natural para hombres son altamente efectivos en la prevención de enfermedades de transmisión sexual, incluido el SIDA (infección del VIH), de ser usados correctamente. Si usted no va a utilizar un condón de látex de caucho natural masculino, puede usar el Condón Femenino FC2 para protegerse usted y proteger a su pareja.

P. ¿Cómo se cuida el Condón Femenino FC2 está ablando con la profundidad correcta?

R. Con el dedo índice empuje el dispositivo de manera que el anillo inferior se ubique contra el pubis. Encontrará el pubis curvando su dedo índice cuando esté a pocas pulgadas dentro de la vagina.

P. ¿Qué hago si el anillo externo ingresa dentro de la vagina?

R. DETÉNGASE. Retire el Condón Femenino FC2 e inserte uno nuevo según las instrucciones.

P. ¿Sintiré el Condón Femenino FC2 una vez que esté ubicado en su lugar?

R. Si es posible que lo note.

P. ¿Qué hago si el pene se inserta fuera del condón femenino?

R. Debe pedirle a su pareja que lo retire y la ayuda a reinsertarlo dentro del condón.

P. ¿El Condón Femenino FC2 se rasgará o se romperá mientras lo estoy usando?

R. Los estudios demuestran que el Condón Femenino FC2 se rasga o rompe en menos de un 1% de las veces. Si cree que el Condón Femenino FC2 se ha rasgado o roto, retírelo de inmediato, deséchelo e inserte uno nuevo.

P. ¿El Condón Femenino FC2 se amontonará dentro de la vagina?

R. amontonarse dentro si se inserta de manera correcta. Si siente que el anillo exterior comienza a deslizarse hacia adentro, DETÉNGASE. Retire el Condón Femenino FC2 e inserte uno nuevo según las instrucciones.

P. ¿Cómo se siente el anillo exterior durante la relación sexual?

R. Aunque sienten el anillo exterior, la mayoría de las mujeres afirman que no interfiere con la relación sexual.

P. ¿Qué hago si el Condón Femenino FC2 no se mantiene en su lugar durante la relación sexual?

R. Si el Condón Femenino FC2 se mueve hacia adentro de la vagina y causa incomodidad, empuje hacia adentro o retire el Condón Femenino FC2. Si lo hace, utilice uno nuevo.

¿TIENE ALGUNA PREGUNTA SOBRE EL MODO DE USO DEL CONDÓN FEMENINO? Llame a su proveedor de salud o comuníquese al 1-800-274-6601

CÓMO UTILIZAR EL CONDÓN FEMENINO FC2

1 PARA ABRIR EL PAQUETE

- Es importante también que el anillo externo esté fuera de los labios externos de la vagina como se muestra en la Fig. F.
- Alrededor de una pulgada del extremo abierto quedará fuera de su cuerpo. Fig. F. Si bien esto puede parecer poco usual, es esta parte del Condón Femenino FC2 la que ayuda a protegerlo a usted y a su pareja durante el sexo. Una vez que el pene se introduce, la vagina se expande y no quedará ya suelto el condón.

2 PARA INTRODUCIR EL CONDÓN FEMENINO FC2

- Encuentre una posición cómoda. Intente pararse con un pie sobre una silla, siéntese con las rodillas separadas o ubíquese en cuclillas.
- Asegúrese de que el anillo interno está en el extremo cerrado inferior de la bolsa. Fig. B
- Sujete la bolsa de plástico con el extremo abierto hacia abajo. Al sujetar la parte exterior de la bolsa, apriete el anillo interno con sus dedos pulgar y medio.
- Coloque su dedo índice entre el pulgar y el dedo medio y siga apretando el anillo interno (Fig. C (b)).
- Mientras está apretando el Condón Femenino FC2, con la otra mano, separe los labios de la vagina como si se estuviera preparando para introducir un tampón.

3

- Hasta que usted y su pareja se familiaricen con el Condón Femenino FC2, use su mano para guiar al pene hacia la vagina. Vea la FIG. G.
- Luego de usarlo dos o tres veces, ya se habrán familiarizado con el Condón Femenino FC2 y apenas notarán la bolsa o el anillo externo durante la relación sexual.

6 DURANTE LA RELACIÓN SEXUAL

- Quizás note que el Condón Femenino FC2 se mueve durante la relación sexual. Vea la FIG. H.



7 LUGO DE LA RELACIÓN SEXUAL

- Para sacarse el Condón Femenino FC2, apriete y retuerza el anillo externo para mantener el esperma dentro de la bolsa. Sáquelo suavemente. Arrojelo a un cesto de basura. No lo tire por el inodoro. No lo vuelva a usar. Vea la Fig. K.

RECUERDE

Para ayudar a reducir el riesgo de embarazo y el contagio de enfermedades de transmisión sexual:

- Utilice el Condón Femenino FC2 correctamente cada vez que tenga relaciones sexuales.
- Siga las instrucciones atentamente.
- Asegúrese de no romper el condón FC2 con sus uñas ni con otros objetos cortantes.

