

The Need for Woman Controlled Contraceptive Methods for Dual Protection



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www.fc2.us.com

Moderator: Margaret Semisch McCann, MSN, CRNP, WHNP-BC

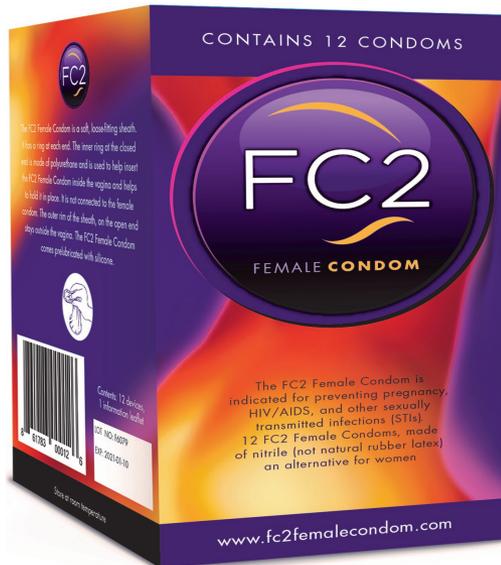
Beth Kelsey, EdD, APRN, WHNP-BC, FAANP is a board certified women's health nurse practitioner. She is currently assistant professor at Ball State University School of Nursing teaching in their master's in nursing and DNP programs.

Dr. Kelsey is the editor-in-chief of Women's Healthcare: A Clinical Journal for NPs. She is also director of publications for NPWH.



FC2 is an over-the-counter form of contraception that is covered by most insurances with **no out-of-pocket expenses** when prescribed by a physician.

- **FC2 is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs)**
- **FC2 is the only FDA approved female condom**



RX Sample

Patient Name: _____

Rx: FC2 Female Condom (12 condoms)

Sig: Use per packaging instructions with each act of intercourse

Disp: 2 Refills: 11

_____, MD

Agenda For Today

- 1 What is FC2
- 2 How to use FC2
- 3 Why FC2
- 4 Talking with Patients about FC2
- 5 FC2 and Prescription

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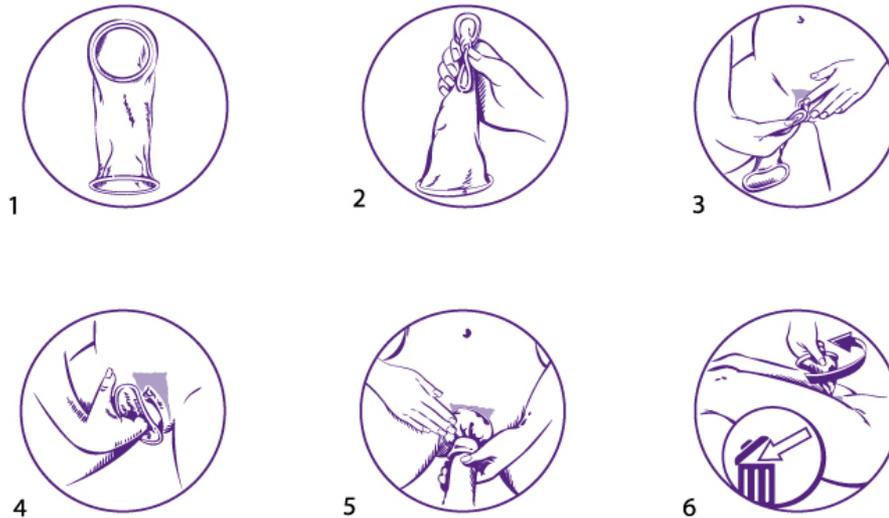
What is FC2

FC2 is the **ONLY** woman controlled dual protection method

- FC2 is the *ONLY FDA* approved female condom
 - Approved as a Class III medical device
- FC2 is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs)
- A *non-hormonal, latex-free* condom inserted into the vagina
- Made of *nitrile* (non-latex) sheath and outer ring, and a polyurethane inner ring.
 - *Nitrile* is three times stronger than latex
- Lubricated with a silicone-based lubricant both inside and out
 - *Can be used* with water based and oil based lubricants
- Can be inserted up to *2 hours in advance*
- Includes *no* spermicidal additives
- *Preservative and Paraben free*, Gluten free, non-allergenic

How to Use FC2

The FC2 Female Condom is easy to learn how to use. Demonstrate or explain to your patients how to properly insert the FC2.



Check out the how-to-use resources on the FC2 US site:
<https://fc2.us.com/how-to-use/>

Dr. Sherry

Sheryl A. Ross, M.D., “[Dr. Sherry](#),” is an award-winning OBGYN, entrepreneur, author and women’s health expert. She has been a practicing OB/GYN for 25 years in Santa Monica, California. *The Hollywood Reporter* named her as one of the best doctors in Los Angeles, *Castle Connolly* named her as a *Top Doctor and Exceptional Women* in the specialty of Obstetrics & Gynecology and was selected as a 2017/2018 Southern California Super Doctor. She is the author of the book, *she-ology: The Definitive Guide to Women’s Intimate Health. Period.* And Co-founder of [Cycl](#), the first of its kind wellness brand for women by women based on the 7 distinct and individualized cycles women experience in their lives. Dr. Sherry's mission is to change the narrative of how women talk and learn about their intimate health and overall well-being. You can follow her on Twitter [@DrSherylRoss](#), Instagram [@drsherryr](#) and on Facebook [DrSherryR](#).



STIs 2017

- Most Contagious Diseases in the U.S.
- Most Common: Chlamydia, Gonorrhea, Herpes, HPV, HIV, Syphilis, Trichomoniasis, and Hepatitis
- HPV: Epidemic!
- Zika: New Kid on the Block in this Category
- STIs Effects Women of ALL Ages
- Safe Sex: Do You Know the Definition?
- Condoms: Best Bet in PREVENTING STIs!

Safe Sex?

- Safe sex means using condoms during vaginal or anal intercourse and oral sex (during which dental dams are used to protect the throat from HPV).
- FC2 is a woman's way of ensuring she is having safe sex.
- FC2 is the best way to prevent STIs from spreading.
- The best offense is a good defense!

The Trifecta!

Chlamydia, Gonorrhea and Syphilis

- Chlamydia, gonorrhea and syphilis are the three most commonly reported conditions in the nation and have reached a record high level
- **In 2015**, the total combined cases of chlamydia, gonorrhea, and syphilis reported **reached the highest number ever**, according to the annual *Sexually Transmitted Disease Surveillance Report* released by the Centers for Disease Control and Prevention (CDC).
- There were more than:

1.5 million chlamydia cases reported (increase of 5.9%)

395,216 cases of gonorrhea (increase of 12.8%)

25,000 cases of primary syphilis (increase of 19%)

23,000 cases of secondary syphilis (increase of 19%)

Most Common STIs Reported

- Rates of STIs are at epidemic levels
- **STIs cost healthcare system \$16 billion annually**
- “STI prevention resources across the nation are stretched thin, and we’re beginning to see people slip through the public health safety net. Turning the STI epidemics around requires bolstering prevention efforts and addressing new challenges – but the payoff is substantial in terms of improving health, reducing disparities and saving billions of dollars.”

Dr Jonathan Merin, Director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STI, and TB Prevention

Costs of STIs is Epidemic!

- **2015** cost of STDs are at epidemic levels
- Americans **ages 15 to 24 years old** accounted for nearly **2/3** of chlamydia diagnoses and **half** of gonorrhea diagnoses
- Men who have sex with men (MSM) accounted for the majority of new gonorrhea and P&S syphilis cases (82 percent of male cases with known gender of sex partner). Antibiotic-resistant gonorrhea may be higher among MSM
- Women's rate of syphilis diagnosis **increased by more than 27 percent from 2014 to 2015**. Reported congenital syphilis (which occurs when the infection is transmitted from a pregnant woman to her baby) increased by 6 percent. Women still account for less than 10 percent of new P&S syphilis infections

Most Common STI is HPV

- Epidemic & Highly Contagious
- 90% of women 80% of men
- Precancerous and cancer changes in Cervix, Anus, Penis, Head, Neck & Throat
- HPV Vaccination
- Most people are unaware they carry HPV
- Who's at risk? Multiple sex partners, smoking, poor diet and certain medications lower immune system
- Never goes away
- Condoms - FC2!

What about the ZIKA virus?



- ZIKA virus is spread to people primarily through the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*).
- Zika can be spread through sex with an infected person, pregnant woman to her fetus and blood transfusion.
- Lifetime cost of care for microcephalic child is \$1million (short term) to \$10 million (lifelong)
- No report of infants getting Zika through breastfeeding

ZIKA CDC & ACOG

- ZIKA virus can be transmitted through sex without a condom (present in semen for 6 months)
- Pregnant women should be advised to consistently and correctly use condoms during sex or abstain from sex for the duration of the pregnancy.



FC2-A Game Changer!

FC2 empowers women to take control over their sexual protection

- FC2 provides protection from unintended pregnancy and sexually transmitted diseases including HIV and Zika.
- Can be inserted hours before sex occurs, eliminating the negotiation with men

FC2 is the ONLY female condom that is approved by the FDA for market

FC2 is a hormone-free and latex-free

FC2 is covered, with \$0 co-pay, by most insurance plans when dispensed by prescription

Benefits of FC2

FC2 Increases Protected Sex Act:

- FC2 female condoms, when offered alongside male condoms, increase the number of protected sex acts
- When there is more choice, there is more protected sex

FC2 is Effective:

- In FDA safety & efficacy studies, FC2 was found to be 95% effective as a barrier contraceptive.
- With over 20 years of independent safety, effectiveness, and acceptability research, other data is available demonstrating an efficacy as high as 98%.

FC2 Saves Money:

- A female condom program in Washington DC prevented enough infections in its first year to save more than \$8 million in future medical costs.

FC2 + LARC/SARC



Pregnancy
Prevention



Pregnancy prevention
and STI prevention



PrEP
(HIV prevention)



HIV prevention, STI prevention and
unplanned pregnancy prevention

Stealthing!?

“Stealthing”: Removal of a condom during penetrative sex without a partner’s consent



Reconsidering the Female Condom

Old versions were poorly designed and hard to find—hence, a lack of enthusiasm (and use) among women, says Harry Fisch, MD, a clinical professor of urology and reproductive medicine at the Weill Cornell Medical College and chief corporate officer at the Female Health Company, makers of the FC2 female condom. Newer, improved lady sheaths adhere to the walls of the vagina, are 95 percent effective at protecting against pregnancy and STIs, and are available at many health clinics or through an Rx from a doctor. (The FC2 is the only

HOW TO PROTECT YOURSELF

Before you get into bed with any new partner, come prepared with your own condoms, male or female (see “Reconsidering the Female Condom,” above), and have a candid convo about expectations. If a guy whines about wrapping it up and you don’t know (or trust) him well, think about avoiding intercourse. “If it’s an orgasm you’re after, there are plenty of other ways to get it,” says Pepper Schwartz, PhD, a professor of sociology at the University of Washington at Seattle and coauthor of *50 Great Myths of Human Sexuality*.

How to Talk with Patients

- FC2 is a **non-hormonal, latex-free** device that offers dual protection against STIs and unplanned pregnancy.
- FC2 contains a silicone-based **lubricant** but additional lubrication can be used. FC2 does not contain spermicidal additives, preservatives, paraben and is gluten free.
- FC2 can increase a woman's sense of **empowerment** as she is taking the initiative to protect herself and her partner.
- FC2 is an **option** for women who have difficulty or discomfort negotiating condom use.
- **Men** do not have to have/ maintain an erection to use FC2.
- FC2 is **covered** by most insurances with an RX.

Brian Groch

Mr. Groch has served as Chief Commercial Officer of the Company since January 2017. Mr. Groch served as Chief Commercial Officer of Telesta Therapeutics Inc., a biotechnology company, from October 2015 until December 2016, overseeing the commercial strategy including, the prelaunch and launch plan for the first immunotherapeutic for bladder cancer in 25 years. From 2014 until 2015, Mr. Groch served as Vice President Market Access for Horizon Therapeutics, Inc., a pharmaceutical company focused on rare diseases. Mr. Groch served as Head of Market Access for Dendreon Corporation, a biotechnology company that developed and launched PROVENGE® for metastatic prostate cancer, from 2010 until 2013. Mr. Groch began his career at Merck & Co., where he rose through the sales and marketing ranks from 1989 to 2002 and was part of the product launches and promotion for ZOCOR®, PRILOSEC®, PLENDIL®, COZAAR®, HYZAAR®, TRUSOPT®, FOSAMAX®, MAXALT® and PROSCAR® (a drug to treat benign prostatic hyperplasia).



How to Talk with Patients: **MatCH Research**

PRACTICE MAKES PERFECT:

National Female Condom Evaluation Study, Conducted by The **MatCH Research Unit** in South Africa

The Female Condom program was launched in 1998 and is one of the largest government-funded programs worldwide.

Over **27 million female condoms** were distributed in **South Africa in 2015 / 2016**

National Department of Health, stated that in the HIV National Strategic Plan (NSP) that one of their aims in attempting to prevent new HIV infections and STDs is to increase access and distribution of female condoms.

The purpose of the study was to gauge the progress of the female condom program



How to Talk with Patients: MatCH Research

Key Results:

- **During their first month interview, 91% of 598 women had made use of the female condom** and the remaining number who had not used it, cited reasons such as it was difficult to use and their partners refused to use it.
- In the last year 66.7% of providers reported that they had never or rarely counseled / given FC2 to men. In the last month, 39% of providers discussed FC2 use in one-on-one interactions with female clients compared with 61% who discussed male condom use.
- **80% of women felt that using FC2 placed the women in charge.**
- At one-month interview, most women 87%, **reported that their partners were supportive** of using FC2, and at **six months this rose to 97%**.
- The level of unprotected sex (no male or female condom use) **declined from 43.3% at baseline to 8.4% at 12 months.**
- Men were interviewed and their first month, **58% had said the female condom was either better or much better than the male condom**, and by the 12-month interview, the percentage rose to 74%.

CHANGE STARTS WITH YOU – Data Highlighted the role of the HCP to patient acceptance and utilization.



Prescribing FC2

- Under the ACA, insurance plans are required to cover FC2, with no \$0 out-of-pocket cost.
- FC2 is the only option in the female condom category and is covered by most insurance with \$0 copay.
- You should be able to find FC2 listed in your electronic prescribing systems.
- All retail pharmacies have access to FC2 in their pharmacies including those listed below.
- Uninsured program is available at fc2.us.com

RX Sample

Patient Name: _____

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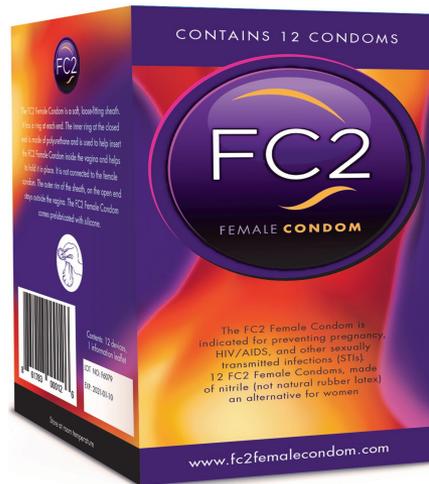
_____, MD

NOT AVAILABLE OTC



SUMMARY

- FC2 is indicated for prevention of pregnancy and STI/HIV and is the only woman controlled dual protection method
- FC2 is the only FDA approved female condom
- FC2 puts women in control of their contraception
- **FC2 is 100% covered under ACA as a contraceptive method**



FC2 | Questions

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