

The Female Health Company (FHC)
FC2 Female Condom
FDA Review of P080002

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PMA Review Team

- Elaine Blyskun, lead review & mechanical testing
- Julia Carey-Corrado, MD, clinical
- Zhiwei Zhang, PhD, statistics
- Heshu Jani Duggirala, PhD, MPH, epidemiology and postmarket plan

PMA Review Team (cont'd)

- Nicholas Benetatos, PhD, polymer chemistry
- Michael Bailey, PhD, biocompatibility
- Alison Cotterell, PhD, microbiology
- James (Pat) Reeves, PhD, prostate specific antigen

PMA Review Team (cont'd)

- Paula Silberberg, labeling
- Patty Jahnes, bioresearch monitoring
- Leslie Caster, manufacturing
- J. Michael Kuchinski, manufacturing

FDA Presentation Outline

- Preclinical Review – Elaine Blyskun
- Clinical Review – Julia Carey-Corrado, MD
- Statistical Review – Zhiwei Zhang, PhD
- Epidemiology Review –
Hesha Jani Duggirala, PhD, MPH

Preclinical Presentation

- History of the PMA Review
- Indications for Use
- Device Description
- Overview of Preclinical Review

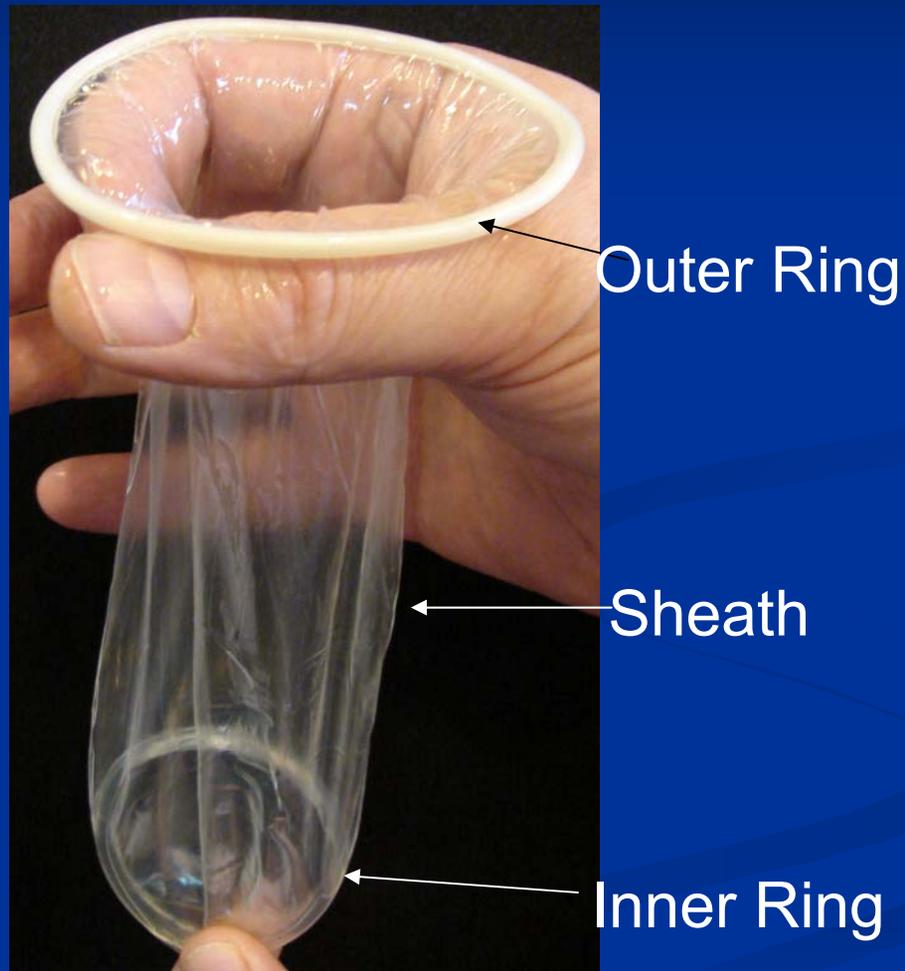
History of FDA Review

- January 8, 2008 – PMA Received
- April 15, 2008 – FDA questions to sponsor
- September 10, 2008 – FHC response
- December 11, 2008 – Panel Meeting

Proposed Indications for Use

The FC2 Female Condom, when used correctly and consistently, helps to prevent HIV/AIDS, other sexually transmitted infections (STIs) and unintended pregnancy.

Device Description



Device Description

FC2 Components

- Inner Ring
 - Polyurethane
 - Same as FC1
 - Aids in insertion

- Sheath
 - Nitrile
 - Dipping Process- no seam

- Outer Ring
 - Nitrile
 - Rolled open end of condom sheath

Device Description

Dimensions of FC1 and FC2

Dimension	FC1	FC2
length (mm)	160-180	164-184
width (mm)	76-82	76-83
sheath thickness (μm)	41-61	65-85
outer ring thickness (mm)	2.33-2.53	2.9-3.8
outer ring, minimum diameter (mm)	67	67
inner ring thickness (mm)	4.60-5.10	4.60-5.10
inner ring diameter (mm)	50.2-50.8	50.2-50.8

Preclinical Review

Nitrile (FC2) and Polyurethane (FC1)

Tensile, Tear Properties

- Nitrile has lower tensile properties and lower tear resistance compared to polyurethane
- FC1 has seam
 - Tensile properties of polyurethane (FC1) as measured across the seam were equivalent to or better than the bulk tensile properties of nitrile (FC2).
- Sponsor increased FC2 thickness

Preclinical Review

Airburst Testing

FC1 and FC2 have equivalent burst properties despite differences in specifications.

Specification	FC1	FC2	% Difference
Airburst Pressure (kPa)	4.80	3.45	-39%
Airburst Volume (L)	4.5	5.0	+10%

Preclinical Review

Comparison: Original and Current FC1

Sponsor compared:

- Burst pressure
- Seam strength
- Tensile strength

Conclusion:

Current FC1 properties as good as or better than original FC1

Preclinical Review

Other Preclinical Tests

- Biocompatibility – acceptable
- Thermal properties – acceptable
- Viral penetration – acceptable
- Bioburden testing – acceptable
- 3-year shelf life – acceptable
- Lubricant compatibility- review ongoing

Preclinical Review

FDA Comments on Preclinical Testing

- FC2 is different from FC1
 - outer ring
 - nitrile
 - softer, more flexible, and thicker
 - sheath
 - nitrile-lower physical properties
 - thicker and no seam
- Difficult to predict clinical performance with only bench data
 - Underscores importance of acceptable clinical study

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Objectives

- Historical perspective
- FC2 PMA
 - Why the FC2 PMA is unique
 - Cornerstone of FC2 PMA – the Reality Female Condom (FC1) Pivotal Clinical Trial
 - FDA clinical review of FC2 Clinical Study
- FDA clinical review summary

History of Female Condom

Himes NE. Practical Birth-Control Methods. Modern Age Books, New York. 1938: p. 184

- *“One of the most interesting primitive contraceptive devices was used by ... a tribe living in northern South America, of a sort of female condom. A pod, similar to our milk-weed pod, is cleaned out, one end snipped off, and the closed end inserted into the vagina” (p. 184).*

History of Female Condom

Ref: Beadle EL. A New Method for the Profession. Heminway Press, Waterbury, CT. 1934: p. 12.

- *“The [Gee Bee Ring] method consists of a large sac of prepared animal tissue which is properly fitted in a plicated ring and tested by filling with water.... It is inserted into the vagina by the female with the aid of a test tube, when properly lubricated.”*

FC2 PMA

- Unique aspects
 - Pivotal clinical trial did not evaluate contraceptive effectiveness or STI risk reduction
 - Clinical data obtained outside US
 - Public health impact outside US

FC2 PMA

- Data on contraceptive effectiveness and STI risk reduction inferred from pivotal clinical trial of Reality Female Condom (P910064) – “FC1”
- PMA for FC1 approved in May 1993
 - Testimony during open public hearing re urgent need for female initiated prophylaxis in AIDS epidemic

Summary of Pivotal Clinical Trial of Contraceptive Effectiveness of the Reality Female Condom (FC1)

- Prospective, single arm, multi center, international
- 6-month contraceptive effectiveness study
- Six sites in US
- Three OUS sites (Mexico and Dominican Republic)

Ref: Farr G, Gabelnick H, Sturgen K and Dorflinger L. Contraceptive Efficacy and Acceptability of the Female Condom. Am J Pub Health 1994; 84(12): 1960-1964

FC1: Summary of Pivotal Clinical Trial (US Efficacy Population)

	US Subgroup N=221
Completed Study	147/221 (66.5%)
Discontinued	
-Personal reasons	42/221 (19%)
- Accidental pregnancy	22/221 (10%)
-Medical reasons	4/221 (1.8%)
-Planned pregnancy	1/221 (0.4%)
-Lost to follow-up	5/221 (2.3%)
-Total	74/221 (34%)

FC1: Summary of Pivotal Clinical Trial (cont)

	US Cohort
6-month gross cumulative pregnancy rate	12.4
6-month gross cumulative life table pregnancy rate <i>during perfect use</i>	2.6

FC1: Pregnancy Rates at 12 Months (from FDA-approved labeling)

	Typical Use	Perfect Use
Reality Female Condom (FC1)	21%	5%
Male latex Condom	12%	3%

FC1 – Post PMA Approval

- Over 125 million FC1 devices distributed worldwide
- % women in US relying on FC1 small compared to OUS

Development of FC2

- Goals
 - Lower material and labor cost making female condom more affordable to public health agencies
 - Increase accessibility
 - Maintain design, appearance and instructions for use

FC2 Pivotal Clinical Trial

- Reproductive Health & HIV Research Unit (RHRU) University of Witwatersrand, South Africa
- RHRU Study conducted Jan-Sept 2004
- Pre-IDE not submitted to FDA

FDA Review of RHRU Study

- Design
- Objectives
- Primary Endpoints
- Research Question

→ Panel Discussion Question 1

- Demographics
- Study execution
- Results
- Study Methods for Data Collection

RHRU Study

- Prospective, randomized, “double blinded”, multi-center, crossover study comparing FC1 and FC2
- Objectives
 - Compare rates of clinical and non-clinical breakage, outer ring displacement (invagination), misdirection, slippage and adverse events
 - Compare acceptability of FC2 vs. FC1

RHRU Study

- Primary Endpoint – Rate of Acute Failures FC2 vs. FC1
 - Breakage
 - Slippage
 - Invagination
 - (Penis) mis-direction

RHRU Study

- Research Question

- *“The expected outcomes of the study from the reference condom (FC1) was a breakage rate of less than 5%.... If the breakage rate for FC2 exceeds this standard, the new condom will not be considered for further development and testing.”*

Panel Discussion Question 1

RHRU Study

- Inclusion Criteria
 - ≥ 18 years
 - Not pregnant or nursing
 - Currently using hormonal contraceptive, IUD or tubal ligation
 - Sexually active
 - Good general/gynecological health

RHRU Study

- Exclusion Criteria
 - Known or suspected active STI
 - Allergic/sensitive to silicone/latex/vaginal lubricant
 - Within 6 weeks postpartum or postabortal

RHRU Study

- Study Population
 - Family planning clinics (Durban)
 - Students (Durban Institute of Technology)
 - STI clients (Durban)
 - Commercial sex workers
 - Rural family planning clients (Umbumbulu Clinic, KwaZulu-Natal)

RHRU Study

- Prior to condom use:
 - Study nurse briefed subjects on responsibilities and procedures
 - Verbal instructions for inserting and removing female condoms
 - Education re need to use female condom correctly

RHRU Study

- Subject responsibilities
 - Accept random assignment to sequence of use of FC1 or FC2
 - Use 10 of each type of condom with partner within 2-3 month study period
 - Complete coital log
 - Return for follow-up after 10 uses of each type of condom

RHRU Study

- Follow up visit
 - Interview (to fill in Questionnaire items)
 - Number of female condoms used
 - Regular or casual partner
 - Functional performance of condom during use
 - Adverse events
 - Acceptability criteria
 - Vulva inspection for evidence of irritation

RHRU Study - Demographics

	Students N=65	Urban FP N=64	Rural FP N=67	STI N=21	CSW N=59	Total N=276
Mean Age (yrs)	23	34	28	35	27	28
Regular Partner (%)	85	55	64	48	25	57
Mean Education (Grade level)	11.2	10.6	10.0	11.4	9.7	10.5
Employment	5%	41%	0%	62%	3%	16%

RHRU Study Subjects – Contraceptive Use

	Students N=65	Urban FP N=64	Rural FP N=67	STI Clinic N=21	CSW N=59	Total N=276
OCs	21/65 (32%)	13/64 (20%)	7/67 (10%)	4/21 (19%)	5/59 (9%)	49/276 (18%)
Injectables	44/65 (67%)	42/64 (66%)	57/67 (85%)	10/21 (48%)	52/59 (88%)	205/276 (74%)
IUD	0/65 (0%)	0/64 (0%)	2/67 (3%)	1/21 (5%)	1/59 (2%)	4/276 (2%)
Sterilization	1.5/65 (2%)	9/64 (14%)	2/67 (3%)	6/21 (29%)	1/59 (2%)	19/276 (7%)
Male condom	28/65 (43%)	2/64 (3%)	19/67 (28%)	3/21 (14%)	47/59 (80%)	100/276 (36%)
Female condom	2/65 (3%)	7/64 (11%)	0/67 (0%)	2/21 (10%)	5/59 (9%)	16/276 (6%)

RHRU Study - Results

- Enrolled 276
- Completed 1st follow up visit 233
- Completed 2nd follow up visit 201

Subject Accountability

Return Visits	Students N=65	Urban FP N=64	Rural FP N=67	STI Clinic N=21	CSW N=59	Total N=276
1 st F/U Visit	47/65 (72%)	51/64 (79%)	64/67 (95%)	17/21 (81%)	54/59 (92%)	233/276 (84%)
2 nd F/U Visit	41/65 (62%)	41/64 (64%)	55/67 (63%)	13/21 (62%)	51/59 (86%)	201/276 (73%)

Acute Failures Per Condom Use

	FC1	FC2	Difference
Clinical Breakage	9/1910 (0.47%)	8/1881 (0.43%)	-0.04%
Slippage	4/1910 (0.21%)	2/1881 (0.11%)	-0.10%
Complete Invagination	10/1910 (0.52%)	17/1881 (0.90%)	0.38%
Misdirection	24/1910 (1.26%)	12/1881 (0.64%)	-0.62%
Total failures	47/1910 (2.46%)	39/1881 (2.07%)	-0.39%

(FC1 Failure Mode Event Rates Per Condom Use Reported in Literature)

	Break/Rip	Slippage	Misdirect	Invag	Total
Macaluso et al (2003) n=175	0.7%	6%	2%	3%	11.7%
Galvao et al (2005) N=400	--	--	--	--	6%
Valappil et al (2005) N=869	0.11%	2.8%	--	2.8%	5.6%
Chen et al (2007) UAB n=108	0.2%	11%	0.3%	5%	16.5%
Chen et al (2007) UNICAMP n=400	0.3%	2%	5%	1%	8.3%
Macaluso et al (2007) N=108	0.3%	10.6%	5.6%	3.0%	19.5%

RHRU Study – Acute Failures Per Subject

	While Using FC1 (N=218)	While Using FC2 (N=216)
Clinical Breakage	5/218 (2.3%)	7/216 (3.2%)
Slippage	3/218 (1.4%)	2/216 (0.93%)
Complete Invagination	8/218 3.7%)	11/216 (5.1%)
Misdirection	19/218 (8.7%)	11/216 (5.1%)

Invagination – “Outer Ring Displacement” Per Condom

	FC1 N=1910	FC2 N=1881
Complete Displacement	10/1910 (0.52%)	17/1881 (0.90%)
Partial Displacement	50/1910 (2.62%)	39/1881 (2.07%)
Total Displacement	60/1910 (3.14%)	56/1881 (2.98%)

Invagination – “Outer Ring Displacement” Per Subject

	FC1 N=218	FC2 N=216
Complete Displacement	8/218 (3.67%)	11/216 (5.09%)
Partial Displacement	42/218 (19.2%)	29/216 (13.4%)
Total “Displacers”	50/218 (23%)	40/216 (18.5%)

RHRU Study – Invagination (Outer Ring Displacement)

- Possible problem with inserting condom too far into vagina; Penis may push outer ring into vagina

“We recommend that instructions on proper placement should include that outer ring be held by woman during insertion and that couple be aware of outer ring during sex to ensure it does not get pushed inside vagina.”

RHRU Study – Adverse Events

	FC1 N=218	FC2 N=216
Discomfort during insertion	13.8%	13.0%
Discomfort after insertion before sex	3.2%	1.9%
Pain after insertion before sex	1.4%	2.3%
Pressure/urge to urinate	0.9%	0%
Discomfort during sex	1.4%	<1%
Uncomfortable to use	5%	2.3%
Burning/rash/itching	0%	2.3%
Bleeding	0%	<1%
Confirmed STI	<1%	0%

Methods for Data Collection

- Coital Log
 - Complement Study Questionnaire
 - Reference during follow-up visit
- Possible Limitations of Coital Logs
 - All data for each phase of study entered on single page
 - No entry for “slippage”
 - Not designed to record number of failures on days when >1 female condom was used
 - 38% missing coital logs
 - Among 434 follow-up visits, 266 coital logs were returned and 168 were “missing”

Coital Log

Day of week	Week 1							Week 2						
	M	T	W	T	F	S	S	M	T	W	T	F	S	S
1. Menstrual bleeding 0 = none B = bleeding														
2. Number of acts of intercourse (0, 1, 2, 3 etc.)	0													
3. Female condom														
(a) Number used	0													
(b) no problem	<input type="checkbox"/>													
(c) slip during use/ broke	<input type="checkbox"/>													
(d) pushed into vagina	<input type="checkbox"/>													
(e) penis inserted outside condom	<input type="checkbox"/>													

Coital Log Completion per Follow-up Visit

	Student N= 88	Urban FP N=92	Rural FP N=119	STI Clinic N=30	CSW N=105	Total F/U Visits N=434
Visits with coital log	65/88 (74%)	80/92 (87%)	100/119 (84%)	21/30 (70%)	0/105 (0%)	266/434 (61%)
Visits w/o coital log	23/88 (26%)	12/92 (13%)	19/119 (17%)	9/30 (30%)	105/10 5 (100%)	168/434 (39%)

Study Questionnaire

- Completed during follow-up interview
- Time lag between condom use and interview

- 56 Questions:
 - Sociodemographic (8)
 - Experience with Female Condom (9)
 - number
 - partner
 - insertion
 - Comfort (11)
 - Removal (4)
 - Stability (5)
 - Acceptability (19)

Study Questionnaire

Q307 “Did the female condom stay in place every time during intercourse?”

Q308 “If no, what happened?”

RHRU Study – Potential Problems with Data Collection

- Missing coital logs (38%)
- RHRU coital log did not provide for recording > 1 failure (e.g. when more than one condom was used per day)
- RHRU coital log did not include entry for slippage
- Single page for reporting of each study phase

RHRU Study - Potential for Under-reporting of Failure Modes

- Lost-to-follow up
 - Face-to-face interviews to complete Questionnaire
 - Lag time between coitus and interview
 - Use of CSWs
 - Less prone to failure
 - Did not complete coital log
- difficult to quantify potential impact on study conclusions

Panel Discussion Question 2

Panel Discussion Question 3

Summary

- RHRU Study not a contraceptive effectiveness or STI risk reduction study
- Contraceptive efficacy and STI risk reduction attributable to FC1 have been examined in clinical and epidemiology studies
- Acute failure rates for FC1 and FC2 comparable in RHRU study
- Coital log limitations and potential that failure rates are underreported in the RHRU study

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- Epidemiology Review –
Hesha Jani Duggirala, PhD, MPH

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FC2 Female Condom
FDA Statistical Review of P080002

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Outline

- Study design
- Patient accountability
- Study results
- Interpretation
- Summary

Study Design

- 276 women from five subgroups
- Randomized, crossover design
- 10 FC1 followed by 10 FC2 or the opposite
- One coital log for all condoms of each type
- One interview for each condom type
- Data based on interviews (with or without coital logs)

Patient Accountability

Group	Students		Urban FP		Rural FP		STI		CSW		Total	
	%	N	%	N	%	N	%	N	%	N	%	N
Randomized	100	(65)	100	(64)	100	(67)	100	(21)	100	(59)	100	(276)
1st follow-up	72	(47)	79	(51)	95	(64)	81	(17)	92	(54)	84	(233)
2nd follow-up	62	(41)	67	(41)	88	(55)	62	(13)	83	(51)	73	(201)

Key Failure Modes

- Clinical breakage
- Misdirection
- Complete invagination
- Complete slippage
- Total clinical failure

Estimated Failure Rates and Differences

Failure mode	Failure rate (%)		Difference	
	FC1	FC2	FC2 - FC1	95% CI
Clinical breakage	0.47	0.43	-0.04	(-0.62, 0.53)
Misdirection	1.26	0.64	-0.62	(-1.33, 0.09)
Complete invagination	0.52	0.90	0.38	(-0.25, 1.01)
Complete slippage	0.21	0.11	-0.10	(-0.39, 0.19)
Total Clinical Failure	2.46	2.07	-0.39	(-1.67, 0.89)



condom uses: 1910 (FC1); 1881 (FC2)

Statistical Ramifications of Clinical Issues

- Issues with data collection
 - Coital log design
 - Non-use of coital logs
 - Time between condom use and interview
 - Loss to follow-up
- The above issues could have
 - Resulted in underreporting, hence the relatively low failure rates.
 - Complicated the comparison of FC2 with FC1.

Hypotheses for Comparative Inference

- Not pre-specified.
- Could test for non-inferiority, i.e., that FC2 is not worse than FC1 by more than a specified amount “delta”.
- What is delta?
 - Undetermined for female condoms.
 - A 2% delta is commonly used for male condoms.

Estimated Failure Rates and Differences

Failure mode	Failure rate (%)		Difference	
	FC1	FC2	FC2 - FC1	95% CI
Clinical breakage	0.47	0.43	-0.04	(-0.62, 0.53)
Misdirection	1.26	0.64	-0.62	(-1.33, 0.09)
Complete invagination	0.52	0.90	0.38	(-0.25, 1.01)
Complete slippage	0.21	0.11	-0.10	(-0.39, 0.19)
Total Clinical Failure	2.46	2.07	-0.39	(-1.67, 0.89)

Commercial Sex Workers (CSWs)

- May have been more experienced with female condoms.
- May have had more difficulties remembering events, with frequent sex acts and without using coital logs.
- May have had different failure rates than the rest of the study cohort.

Analysis Excluding CSWs

Failure mode	Failure rate (%)		Difference	
	FC1	FC2	FC2 - FC1	95% CI
Clinical breakage	0.54	0.54	0.00	(-0.73, 0.73)
Misdirection	1.63	0.68	-0.95	(-1.84, -0.06)
Complete invagination	0.48	0.88	0.41	(-0.27, 1.09)
Complete slippage	0.27	0.07	-0.20	(-0.55, 0.15)
Total Clinical Failure	2.92	2.18	-0.74	(-2.29, 0.81)

Summary

- Low failure rates may have resulted from underreporting.
- Based on the available data, FC2 appears non-inferior to FC1 with respect to acute failure rates for a 2% delta.
- No evidence that FC2 is superior to FC1 with respect to acute failure rates.
- No empirical evidence regarding contraception and STI risk reduction.

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FC1 Epidemiologic Studies

Study	Results	Limitations
Trussell	0.8% 6 month pregnancy probability	<ul style="list-style-type: none"> ▪ Lower coital frequency ▪ Sample size
French	6.8% STI incidence	<ul style="list-style-type: none"> ▪ Male condom use in female condom arm
Fontanet	24% reduction in STI rates	<ul style="list-style-type: none"> ▪ Unrepresentative sample
Macaluso	Female condoms at least as effective	<ul style="list-style-type: none"> ▪ No separation of male condom effect
Hoke	STI prevalence dropped from 52% to 40%	<ul style="list-style-type: none"> ▪ Unclear if male condoms also used
Feldblum	No change in STI prevention	<ul style="list-style-type: none"> ▪ No separation of male condom effect

FC1 Epidemiologic Studies: Trussell study

- The 6-month life table probability of becoming pregnant was 3.2% during typical use and 0.8% during correct and consistent use of the female condom
- Lower coital frequency in this cohort may account for the lower risk of pregnancy
- No mention as to whether the sample size of 195 subjects is sufficient to compare contraception rates

FC1 Epidemiologic Studies: French study

- Incidence rates for the first new post-intervention STI per 100 women-months of observation were 6.8 in the female condom group and 8.5 in the male condom group
- Male condoms accounted for 1/3 of condom protected sex acts in the female condom study arm

FC1 Epidemiologic Studies: Fontanet study

- 24% reduction in incidence rate of STIs in the sex establishments of the male/female condom group compared to the male condom group
- Thailand has a 100% condom use policy that is strictly enforced and therefore results may not be generalizable to other countries

FC1 Epidemiologic Studies: Macaluso findings

- Consistent and correct use of either condom was associated with a 70% reduction in STI rates as compared to inconsistent use
- Concluded that the female condom appears to be at least as effective as the male condom as a barrier to STI
- Design fails to separate the effect of the female condom from the male condom, and therefore cannot provide any evidence of equivalence between the two

FC1 Epidemiologic Studies: Hoke study

- With the female condom added, STI prevalence dropped from 52% at baseline to 41% at months 12
- The longitudinal design makes it difficult to assess whether increased knowledge and awareness after the male condom phase may have influenced the female condom phase results
- Unclear of male condom impact in the second phase

FC1 Epidemiologic Studies: Feldblum study

- Measure the impact on STI prevalence of a female condom introduction and risk-reduction program
- Investigators concluded that the female condom introduction did not enhance STI prevention at these sites

FC1 Epidemiologic Studies: Other studies

- Macaluso 2000 and Musaba 1998 do not look at FC1 effectiveness but more on acceptability
- These studies do not appear to be relevant to effectiveness

Macaluso M, Demand M, Artz L, et al. Am J Epidemiol. 2000 May-Jun;32(3):138-44.

Musaba E, Morrison CS, Sunkutu MR, et al. Sex Transm Dis. 1998 May;25(5):260-4.

FC2 Postmarket Plan

- All procedures as stated in the Quality Systems performance standard references will be followed for release of product, recording all customer complaints, following MDR and product recall requirements
- Sponsor will provide annually, summary and bibliography of:
 - unpublished reports of data from any clinical investigations or non clinical laboratory studies involving the device or related devices and known to the applicant
 - reports in scientific literature concerning the device

FC2 Postmarket Plan

- The sponsor has not proposed a post-approval study
- Please note that post-approval studies are used to evaluate long-term, real world uses of devices
- Post-approval studies should not be used to evaluate unresolved issues from the premarket phase that are important to the initial establishment of device safety and effectiveness

Conclusions

- Epidemiologic studies show a trend toward STI risk reduction associated with FC1 use
- Effectiveness literature on FC1 has methodologic limitations