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**PRODUCT REFINEMENT EVALUATION FOR THE
DEVELOPMENT OF A PLASTIC CONDOM PROTOTYPE: TWIN
APERTURE (SLIP-ON CONDOM) DESIGN**

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**PRODUCT REFINEMENT EVALUATION FOR THE DEVELOPMENT OF A PLASTIC
CONDOM PROTOTYPE: TWIN APERTURE (SLIP-ON CONDOM) DESIGN**

GENERAL INFORMATION

Study Products

This study evaluated three iterations of the twin-aperture (slip-on) condom design. All study products were 7 1/2 inches long, had 1 1/8 inch diameter apertures, were lubricated with 1/2 cc of GE 200cp silicone oil and were packaged in white cello film. The condoms differed in their materials of construction and processing. A detailed description of each condom type is as follows:

Condom B (FHI Lot 1043B): The condom sheath was made of 35 μ thickness, Deerfield Kraton/polyurethane blend (roll 154A), cut 2 1/2 inches wide on the #005 die. The 35 μ sheath was stress-softened in the 4 1/2 inch tube at 2 1/2 psi to a thickness of 20 μ to 25 μ . The condom flange was 35 μ Deerfield Kraton.

Condom C (FHI Lot 1044B): The condom sheath and flange were made of 35 μ thickness, Deerfield Kraton/polyurethane blend (roll 154A), cut 3 inches wide on the #009 die. The condom sheath was **not** stress-softened.

Condom D (FHI Lot 1056B): The condom flange was 25 μ thickness Elastollan polyetherurethane (roll 102). The condom sheath was made of the same polyetherurethane in 50 μ thickness, cut 2 1/4 inches wide with the #013 die. The condom sheath was stress-softened from 50 μ to 30 μ thickness in the 4 1/2 tube at 3 3/4 psi.

Study Design

The study was divided into three distinct evaluation cells (ie. one group of couples tested condoms B and C, another tested B and D, and a third tested C and D). Each couple tested one condom of each of the two types within their assigned cell. Forty couples were recruited to evaluate the study products.

The objectives of the study were to determine: (1) the overall acceptability of each condom type; (2) the preference for one condom type over another; and (3) which of the three condom iterations performed best in terms of breakage and slippage.

RESULTS

Sociodemographic Characteristics

A total of 40 couples completed this study (Table 1). Female participants were younger than their male counterparts (median age 31 years vs. 34 years) with slightly less education (14 years vs. 15 years). Over ninety percent of both males and female were white.

Almost all participants reported having used condoms during their lifetime (Table 2). The same proportion of males and females (10%) said they had used more than 100 condoms during their lifetime, while 70 percent of the males reported using between 26 and 100 condoms during their lifetime (vs. 45% of females). Three-fourths (75%) of both males and females said they had used between 10 and 25 condoms in the past year. A majority of participants reported not experiencing any condom breakage in the past year (males=63%, females=58%).

Failure Rates

Participating couples used a total of 27 unblown Kraton condoms (Condom C), 26 blown Kraton condoms (Condom B) and 27 blown Elastollan condoms (Condom D) (Table 3). Participants reported breaking two unblown Kraton condoms (8%), one was a non-clinical break (while donning) and the second break was clinical (during intercourse). Of the four breaks reported with the blown Kraton condoms, two were non-clinical (8%) and two were clinical (8%). Only one blown Elastollan condom was reported to have broken in a non-clinical manner (4%).

Of the condoms that were used in a clinical sense, two of the unblown Kraton condoms were reported to have slipped off (8%), while three (12%) of the blown Kraton and blown Elastollan condoms were reported to have slipped off during intercourse. This resulted in a total failure rate for the unblown Kraton condoms of 15 percent, blown Kraton at 27% and blown Elastollan at 15%.

Condom Acceptability

Tables 4a through 4c provide comparative information on participants' preferences. Table 4a compares unblown Kraton to blown Kraton. Approximately one quarter (23%) of males and 38% of females in this evaluation cell preferred the unblown Kraton. Twelve percent of males and females preferred the blown Kraton. Sixty-six percent of males and 50 percent of females had no preference or did not specify a preference for either of the condoms. Interestingly, more females (58%) than males (46%) could detect a difference between the two condoms types.

Table 4b compares unblown Kraton to blown Elastollan. Thirty-nine percent of males and 29 percent liked the unblown Kraton condom better than the blown Elastollan. Again, 50 percent of males and 54 percent of females had no preference or did not specify a preference for either condom. Fifty-seven percent of males and 54 percent of females could distinguish differences between the two condoms.

Table 4c compares blown Kraton to blown Elastollan. Twice as many males (38% to 17%) and almost three times as many females (31% to 12%) preferred the blown Kraton condom to the blown Elastollan device. As in the other evaluation cells, an unusually high percentage of men (45%) and women (57%) did not specify a preference for either device. Sixty-seven percent of male and 58 percent of female participants were able to discern a difference in the two condoms.

The participants were asked to rate the test condoms along 14 parameters with a five point scale (1-excellent, 2-good, 3-average, 4-below average and 5-poor) (Table 5). Caution must be taken when interpreting this table since the test condoms were not ranked by the same group of couples. The blown Kraton condom received the most favorable mean score from the female participants (2.3), while the male participants judged the unblown Kraton condom to be the most favorable (2.4). The blown Elastollan condom was judged least favorable by both females and males (mean score of 2.6 and 2.8, respectively). Among the male participants, the blown Kraton was judged more difficult to put on (score of 3.3) than the blown Elastollan (score of 3.0) and the unblown Kraton condom (score of 2.7)

About ten percent of the male participants reported problems with the test condoms, while a slightly higher number of female participants voiced complaints (Table 6). The sample size of this study is so small that only a few responses were mentioned more than a couple of times. Five female participants indicated that the extra base material (flange) was "annoying" for the blown Kraton condom. Five females felt that the blown Elastollan material was unpleasant.

When male participants were specifically asked whether they had problems putting on the test condoms, over half (58%) said they had problems with the blown Elastollan condom (Table 7). One-third of the male participants said they had problems putting on the blown Kraton condom, while the fewest (19%) reported problems with putting on the unblown Kraton condom. The most frequent problem cited by nine male participants was that the Elastollan condom "did not slip easily onto the penis".

DISCUSSION

This study was designed to provide information necessary to the development process of the polyurethane condom. Given the small sample size and limited number of devices used in each evaluation cell, caution should be taken in interpreting these data.

There was more reported breakage (4 devices) and a higher total condom failure rate (27%) with the blown Kraton product (Table 3). This was somewhat expected given the thinness of the film (20 μ -25 μ) and the reduced tensile strength resulting from the stress-softening process. Comparable failure rates (15%) were reported for both blown Elastollan and unblown Kraton. There were no reported clinical breakages of blown Elastollan condoms, but these condoms had a higher rate of slippage (12% vs. 8%) than the unblown Kraton devices.

Of those individuals specifying a preference for one condom type over another, males and females both preferred unblown Kraton to blown Kraton, unblown Kraton to blown Elastollan, and blown Kraton to blown Elastollan (Tables 4a through 4c). Most participants (greater than 50% within each evaluation cell) were able to distinguish between the two condom types. This was especially true of males (67%) in the blown Kraton vs. blown Elastollan cell (Table 4c). Interestingly, a high percentage of males (range 47% to 62%, depending on evaluation cell) and females (46% to 58%) expressed that they would possibly buy the study condoms if they were made commercially available.

Overall perception ratings of the condoms were similar for males and females and between condom types (Table 5). As stated in the RESULTS section, women preferred the Kraton condoms to the Elastollan along all parameters evaluated except "feeling of the lubricant" and perceived "strength" of the condom. Similarly, males ranked Kraton better in all aspects but "feeling of the lubricant". Also, male participants rated blown Elastollan slightly higher (3.0 vs. 3.3 where 1-excellent and 5-poor) than blown Kraton. This may be explained in part by the extreme softness of the blown Kraton which combined with the lubricant can produce a "dragging" of the condom across the penis during donning. This phenomena was reported in earlier slip-on condom iterations also.

In general, males and females experienced fewer problems with the unblown Kraton (Table 6). Eight women complained that "material at base of condom was annoying". Interestingly, five of these women complained about the Kraton flange, while only two reported this problem with the Elastollan flange. This is somewhat ironic in that the Elastollan material is much stiffer and presumably more irritating/annoying than Kraton. Five women also complained about the Elastollan material feeling unpleasant.

While the sample size was small and the number of condoms tested was limited, there was a decided trend in participants' preferences for the Kraton condoms for most acceptability parameters studied. The total failure rate (27%) experienced with the blown Kraton condom, combined with its thinness (approximately 20 μ) and the additional processing (stress-softening) required to manufacture it would suggest that blown Kraton may not be a viable candidate for future study. In addition, unblown Kraton was generally more acceptable to both males and females.

Blown Elastollan was the least preferred condom of the three studied, however, it does have superior strength over Kraton and when lubricated sufficiently has comparable acceptability to that of unblown Kraton.

It is recommended that a larger trial be conducted comparing blown Elastollan and unblown Kraton.

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**Table 1: Sociodemographic characteristics of couples
(n=40 couples)**

	Male		Female	
	n	(%)	n	(%)
Age				
< 25	3	(8)	4	(10)
25-29	8	(20)	12	(30)
30-34	14	(35)	11	(28)
35+	15	(38)	12	(30)
Not specified	--	--	1	(2)
Median:	34		31	
Education				
Primary 1-6	--	--	1	(2)
Secondary 7-12	12	(30)	12	(30)
University 13+	28	(70)	27	(68)
Median:	15		14	
Race				
Black	3	(8)	3	(8)
White	37	(92)	37	(92)
NOTE: Percentages in this and all subsequent tables may not equal 100 due to rounding.				

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Table 2: Condom experience of couples
(n=40 couples)

	Male		Female	
	n	(%)	n	(%)
Number of Condoms Used in Lifetime				
10-25	8	(20)	17	(42)
26-100	28	(70)	18	(45)
>100	4	(10)	4	(10)
Not specified	--	--	1	(2)
Number of Condoms Used in Past Year				
None	5	(12)	4	(10)
10-25	30	(75)	30	(75)
26-100	5	(12)	4	(10)
Not specified	--	--	2	(5)
Type of Condom Used in Past Year				
Natural skin	1	(3)	--	--
Latex	20	(57)	19	(53)
Both (skin and latex)	14	(40)	14	(39)
Not specified	--	--	3	(8)
Number of Condoms Broken in Past Year				
0	22	(63)	21	(58)
1-5	10	(28)	11	(30)
6+	3	(23)	2	(6)
Not specified	--	--	2	(6)

Table 3: Condom failure rates of three condoms

	Unblown Kraton		Blown Kraton		Blown Elastollan	
	n	(%)	n	(%)	n	(%)
Number of Condoms Used	27	(100)	26	(100)	27	(100)
Non-Clinical breaks*	1	(4)	2	(8)	1	(4)
Clinical breaks**	1	(4)	2	(8)	--	--
Slipped condoms***	2	(8)	3	(12)	3	(12)
Total failure****	4	(15)	7	(27)	4	(15)
Location of Clinical Breaks						
Tip	--		2		--	
Shaft	1		--		--	
Timing of Slips						
During intercourse	2		1		1	
During withdrawal	--		2		2	

*Condoms that broke while putting the condom on (proportion of all condoms in study).

**Condoms that broke during intercourse (proportion of all condoms that were available for intercourse).

***Condoms that slipped off during intercourse or withdrawal (proportion of all condoms available for intercourse).

****Condoms that slipped or broke (proportion of all condoms in study).

**Table 4a: Participants' Condom Preference
Unblown Kraton (n=26) vs. Blown Kraton (n=24)**

	Males		Females	
	n	(%)	n	(%)
Which condom was liked better?				
Unblown Kraton	6	(23)	9	(38)
Blown Kraton	3	(12)	3	(12)
Neither	3	(12)	2	(8)
Not specified	14	(54)	10	(42)
Were differences detected?				
Yes	12	(46)	14	(58)
No	14	(54)	9	(38)
Not specified	--	--	1	(4)
If available, would you buy either of the two condoms?				
Yes	8	(31)	3	(12)
Possibly	6	(23)	9	(38)
Not sure	2	(8)	1	(4)
Probably not	3	(12)	1	(4)
No	3	(12)	7	(29)
Will not buy condoms	4	(15)	2	(8)
Not specified	--	--	1	(4)

**Table 4b: Participants' Condom Preference
Unblown Kraton (n=26) vs. Blown Elastollan (n=26)**

	Males		Females	
	n	(%)	n	(%)
Which condom was liked better?				
Unblown Kraton	11	(39)	7	(29)
Blown Elastollan	3	(11)	4	(17)
Neither	2	(7)	2	(8)
Not specified	12	(43)	11	(46)
Were differences detected?				
Yes	16	(57)	13	(54)
No	11	(39)	10	(42)
Not specified	1	(4)	1	(4)
If available, would you buy either of the two condoms?				
Yes	5	(18)	6	(25)
Possibly	8	(29)	8	(33)
Not sure	3	(11)	2	(8)
Probably not	3	(11)	2	(8)
No	6	(21)	2	(8)
Will not buy condoms	2	(7)	3	(12)
Not specified	1	(4)	1	(4)

**Table 4c: Participants' Condom Preference
Blown Kraton (n=24) vs. Blown Elastollan (n=26)**

	Males		Females	
	n	(%)	n	(%)
Which condom was liked better?				
Blown Kraton	9	(38)	8	(31)
Blown Elastollan	4	(17)	3	(12)
Neither	3	(12)	4	(15)
Not specified	8	(33)	11	(42)
Were differences detected?				
Yes	16	(67)	15	(58)
No	7	(29)	11	(42)
Not specified	1	(4)	--	--
If available, would you buy either of the two condoms?				
Yes	3	(12)	7	(27)
Possibly	12	(50)	5	(19)
Not sure	1	(4)	3	(12)
Probably not	--	--	1	(4)
No	5	(21)	7	(27)
Will not buy condoms	2	(8)	3	(12)
Not specified	1	(4)	--	--

Table 5: Perception of the condoms

	Unblown Kraton (n=26)	Blown Kraton (n=24)	Blown Elastollan (n=24)
How Well Females Liked:*			
General appearance	2.6	2.3	2.8
Ease of putting on	2.5	2.3	3.2
Comfort of base of condom	2.3	1.9	2.6
Feeling of lubricant	2.6	2.4	2.2
Color of condom	2.4	2.2	2.2
Length of condom	2.4	2.8	2.8
Width of condom	2.5	2.6	2.8
Strength of condom	2.4	2.3	2.1
Odor	2.2	2.2	2.3
Noise	2.2	2.3	2.5
General fit	3.0	2.6	3.2
Comfort in use	2.5	2.2	2.9
Sensitivity	2.5	2.2	2.8
General performance	2.5	2.4	2.8
Overall Mean Score	2.5	2.3	2.6
How Well Males Liked:*			
General appearance	2.6	2.7	3.0
Ease of putting on	2.7	3.3	3.0
Comfort of base of condom	1.9	2.3	2.6
Feeling of lubricant	2.4	2.4	2.2
Color of condom	2.4	2.3	2.5
Length of condom	2.4	2.5	2.9
Width of condom	2.4	2.6	3.0
Strength of condom	2.3	2.3	2.5
Odor	1.9	2.2	2.3
Noise	2.4	2.2	2.8
General fit	2.6	2.7	3.2
Comfort in use	2.4	2.5	2.8
Sensitivity	2.3	2.5	2.8
General performance	2.5	2.4	3.0
Overall Mean Score	2.4	2.5	2.8

*Mean scores based on a scale of 1 to 5 where 1-Excellent, 2-Good, 3-Average, 4-Below average and 5-Poor.

Table 6: General problems with test condoms

	Unblown Kraton (n=26)		Blown Kraton (n=26)		Blown Elastollan (n=24)	
	n	(%)	n	(%)	n	(%)
Did Condom Cause the Male Any Problems?						
Yes	2	(8)	3	(12)	3	(12)
No	24	(92)	21	(88)	23	(88)
Type of Problem*						
Uncomfortable to put on	--		1		--	
Condom was too long	--		2		1	
Extra base material annoying	--		2		1	
Condom pinched skin	--		1		1	
Feel of material unpleasant	--		--		1	
Noise was unpleasant	--		--		1	
Condom was too loose	2		1		3	
Too little lubrication	--		1		--	
Did Condom Cause the Female any Problems?						
Yes	3	(12)	6	(25)	6	(23)
No	22	(85)	18	(75)	18	(77)
Not specified	1	(4)	--	--	--	--
Type of Problem*						
Uncomfortable to put on	--		1		1	
Condom was too long	1		1		--	
Extra base material annoying	1		5		2	
Condom pulled hair	--		1		--	
Feel of material unpleasant	1		3		5	
Odor was unpleasant	--		1		--	
Noise was unpleasant	--		1		2	
Friction	1		2		4	
Condom was too loose	1		2		3	
Too little lubrication	2		3		3	
*More than one response allowable.						

Table 7: Male specific questions about condoms

	Unblown Kraton (n=26)	Blown Kraton (n=26)	Blown Elastollan (n=24)
	n (%)	n (%)	n (%)
Had Problems Putting On Condom			
Yes	5 (19)	8 (33)	15 (58)
No	21 (81)	16 (67)	11 (42)
What Problems Were Experienced*			
Package difficult to open	2	3	1
Handling difficult	--	1	1
Didn't slip easily onto penis	2	3	9
Condom was too short	1	2	2
Instructions unclear	2	3	3
How did Base of Condom Feel?			
Too tight	8 (31)	6 (25)	7 (27)
Just right	17 (65)	16 (67)	17 (65)
Too loose	1 (8)	2 (8)	2 (8)
*More than one response allowable.			

FAMILY HEALTH INTERNATIONAL

MALE QUESTIONNAIRE

Study Title: *Evaluation of Different Test Condoms*

Today's Date: ___/___/___

ID Number: ___/___

General Information:

1. How old are you? ___ years
2. What is the highest grade that you have completed in school?

None	0								
Primary	1	2	3	4	5	6			
Secondary	7	8	9	10	11	12			
University	13	14	15	16	17+				
3. What is your race?
 1. Asian
 2. Black
 3. Hispanic
 4. White
 8. Other, specify _____
4. How many condoms have you ever used during your LIFETIME?
 0. Never used condoms → **SKIP TO FIRST CONDOM SECTION**
 1. Between 10 and 25
 2. Between 26 and 100
 3. More than 100
5. How many condoms have you used in THE PAST YEAR?
 0. Have not used condoms in the past year → **SKIP TO FIRST CONDOM SECTION**
 1. Between 10 and 25
 2. Between 26 and 100
 3. More than 100
6. What type(s) of condoms have you used in THE PAST YEAR?
 1. Natural skin
 2. Latex
 3. Both of the above
7. How many condoms have you had break in THE PAST YEAR?

___ (# of condoms)

COMPLETE THE FOLLOWING QUESTIONS IMMEDIATELY AFTER USING THE FIRST CONDOM

FIRST CONDOM

INSTRUCTIONS: PLEASE ANSWER EVERY QUESTION. Answer only for yourself, not your partner.

1. Circle the color of the dot that appears on the condom package. (Your packet contains only two condoms)
 1. Red
 2. Blue
 3. Yellow
2. Were you able to use this condom?
 1. Yes → **SKIP TO QUESTION 3**
 2. No
If no, why weren't you able to use it?

SKIP TO FINAL INSTRUCTIONS AT END OF FIRST CONDOM SECTION

3. How well did you like the condom?
 1. Liked it very well
 2. Liked it fairly well
 3. Neutral/no opinion
 4. Somewhat disliked it
 5. Strongly disliked it
4. How would you rank this condom based on the following characteristics? (CIRCLE THE BEST RESPONSE)

	Below				
	Excellent	Good	Average	Average	Poor
General appearance	1	2	3	4	5
Overall design	1	2	3	4	5
Amount of lubricant	1	2	3	4	5
Ease in opening package	1	2	3	4	5
5. How would you rank this condom in EACH of the following categories? (CIRCLE THE BEST RESPONSE)

	Below				
	Excellent	Good	Average	Average	Poor
General appearance	1	2	3	4	5
Ease of putting on	1	2	3	4	5
Comfort of base of condom (open end)	1	2	3	4	5
Feeling of lubricant	1	2	3	4	5
Color of condom	1	2	3	4	5
Length of condom	1	2	3	4	5
Width of condom	1	2	3	4	5
Strength	1	2	3	4	5
Odor (smell)	1	2	3	4	5
Noise	1	2	3	4	5
General fit	1	2	3	4	5
Comfort in use	1	2	3	4	5
Sensitivity	1	2	3	4	5
General performance	1	2	3	4	5

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ID Number: ___ / ___

6. What do you think of the design of this test condom? Please comment on the general **APPEARANCE** of this condom. If you have used other condoms in the past, please compare it to the other condoms you have used.

7. How did this test condom **FEEL** when you used it? If you have used other condoms in the past, please compare it to the other condoms you have used.

8. Did you have any problems putting on on the condom?

0. No **→ SKIP TO QUESTION 9**

1. Yes

If yes, what problems did you have?

(CIRCLE ALL THAT APPLY)

1. Package difficult to open
2. Lubricant made handling condom difficult
3. Condom did not slip on penis easily
4. Condom was too short
5. Base (open end) of condom was too tight
6. Condom was too tight on penis
8. Other, specify _____

9. Did the condom cause you any irritation or discomfort?

0. No **→ SKIP TO QUESTION 10**

1. Yes

If yes, what irritation or discomfort did the condom cause?

(CIRCLE ALL THAT APPLY)

1. Uncomfortable to put on
2. Condom was too long
3. Condom fit, but extra material at base of penis was noticeable
4. Condom pinched skin (tight at base)
5. Condom caught hair
6. Feel of the material was unpleasant
7. Condom smelled bad
8. Noise was unpleasant
9. Too much friction
10. Condom was too loose
11. Too little lubrication
88. Other, specify _____

10. How did the condom feel around the base?

1. Too loose
2. Just right
3. Too tight

11. Did the condom ever slip off?

0. No **→ SKIP TO QUESTION 12**

1. Yes

☑ yes, **WHEN** did the condom slip off?

1. During sex
2. At the end of sex (during withdrawal)
9. Don't know

12. Did the condom break?

0. No **→ STOP, COMPLETE NEXT PAGE IMMEDIATELY AFTER USING SECOND CONDOM**

1. Yes

If yes, **PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS.**

WHERE did the condom break?

1. At the tip (closed end of condom)
2. On the shaft (area between the tip and the base (open end) of the condom)
3. At the base (opening of the condom)
4. At the base (in the extra material around the opening of the condom)
9. Don't know

WHY did the condom break?

1. Condom ripped when opening package
2. Fingernail tore it
3. Carelessness/mishandling
4. Condom too dry
8. Other, specify _____
9. Don't know

IF YOU BREAK A CONDOM, OR THE CONDOM WAS UNUSABLE, PLEASE PLACE THE CLEANED CONDOM INSIDE THE ENCLOSED ZIPLOCK BAG AND COMPLETE THE NEXT PAGE IMMEDIATELY AFTER USING THE SECOND CONDOM

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SECOND CONDOM

MALE QUESTIONNAIRE

INSTRUCTIONS: PLEASE ANSWER EVERY QUESTION. Answer only for yourself, not your partner.

Today's Date: ___/___/___

ID Number: ___/___

1. Circle the color of the dot that appears on the condom package. (*Your packet contains only two condoms*)

1. Red
2. Blue
3. Yellow

2. Were you able to use this condom?

1. Yes **→ SKIP TO QUESTION 3**
2. No

If no, why weren't you able to use it?

SKIP TO FINAL INSTRUCTIONS AT END OF SECOND CONDOM SECTION

3. How well did you like the condom?

1. Liked it very well
2. Liked it fairly well
3. Neutral/no opinion
4. Somewhat disliked it
5. Strongly disliked it

4. How would you rank this condom based on the following characteristics? (**CIRCLE THE BEST RESPONSE**)

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Overall design	1	2	3	4	5
Amount of lubricant	1	2	3	4	5
Ease in opening package	1	2	3	4	5

5. How would you rank this condom in EACH of the following categories? (**CIRCLE THE BEST RESPONSE**)

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Ease of putting on	1	2	3	4	5
Comfort of base of condom (open end)	1	2	3	4	5
Feeling of lubricant	1	2	3	4	5
Color of condom	1	2	3	4	5
Length of condom	1	2	3	4	5
Width of condom	1	2	3	4	5

Question 5 continued.

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
Strength	1	2	3	4	5
Odor (smell)	1	2	3	4	5
Noise	1	2	3	4	5
General fit	1	2	3	4	5
Comfort in use	1	2	3	4	5
Sensitivity	1	2	3	4	5
General performance	1	2	3	4	5

6. What do you think of the design of this test condom? Please comment on the general APPEARANCE of this condom. If you have used other condoms in the past, please compare it to the other condoms you have used.

7. How did this test condom FEEL when you used it? If you have used other condoms in the past, please compare it to the other condoms you have used.

8. Did you have any problems putting on on the condom?

0. No **→ SKIP TO QUESTION 9**

1. Yes

If yes, what problems did you have?

(CIRCLE ALL THAT APPLY)

1. Package difficult to open
 2. Lubricant made handling condom difficult
 3. Condom did not slip onto penis easily
 4. Condom was too short
 5. Base (open end) of condom was too tight
 6. Condom was too tight on penis
 8. Other, specify
-

9. Did the condom cause you any irritation or discomfort?

0. No **→ SKIP TO QUESTION 10**

1. Yes

If yes, what irritation or discomfort did the condom cause?

(CIRCLE ALL THAT APPLY)

1. Uncomfortable to put on
 2. Condom was too long
 3. Condom fit, but extra material at base of penis was noticeable
 4. Condom pinched skin (tight at base)
 5. Condom caught hair
 6. Feel of the material was unpleasant
 7. Condom smelled bad
 8. Noise was unpleasant
 9. Too much friction
 10. Condom was too loose
 11. Too little lubrication
 88. Other, specify
-

ID Number: ___ / ___

10. How did the condom feel around the base?
1. Too loose
 2. Just right
 3. Too tight
11. Did the condom ever slip off?
0. No → **SKIP TO QUESTION 12**
1. Yes
- If yes, **WHEN** did the condom slip off?
1. During sex
 2. At the end of sex (during withdrawal)
 9. Don't know

12. Did the condom break?
0. No → **SKIP TO QUESTION 13**
1. Yes
- If yes, **PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS.**

WHERE did the condom break?

1. At the tip (closed end of condom)
2. On the shaft (area between the tip and the base (open end) of the condom)
3. At the base (opening of the condom)
4. At the base (in the extra material around the opening of the condom)
9. Don't know

WHY did the condom break?

1. Condom ripped when opening package
2. Fingernail tore it
3. Carelessness/mishandling
4. Condom too dry
8. Other, specify _____
9. Don't know

Comparison of the two test condoms:

13. Were the two test condoms different?
0. No → **SKIP TO QUESTION 16**
1. Yes
14. What do you think was/were the difference(s) between the two condoms that you tested?
- (CIRCLE ALL THAT APPLY)**
1. The condoms were different in size (length, width)
 2. The condoms were shaped differently
 3. The condoms were made of different materials
 4. The condoms were of different thicknesses
 8. Other, specify _____
 9. Don't know

15. Of the two condoms that you used, which condom did you like better?
1. First condom
 2. Second condom
 3. Neutral, no preference for either condom
16. If these condoms were available in stores, would you buy them?
1. Yes
 2. Possibly
 3. Not sure
 4. Probably not
 5. No
 6. Will never buy condoms

**THANK YOU FOR PARTICIPATING
IN THIS STUDY!**

**IF YOU BREAK A CONDOM, OR THE
CONDOM WAS UNUSABLE, PLEASE PLACE
THE CLEANED CONDOM INSIDE THE
ENCLOSED ZIPLOCK BAG AND RETURN IT
WITH THE COMPLETED SURVEYS TO THE
CONDOM STUDY GROUP AT FHI**

**PLEASE CHECK TO MAKE SURE
YOU ANSWERED ALL QUESTIONS
BEFORE SENDING IN THE
SURVEYS**

FAMILY HEALTH INTERNATIONAL

FEMALE QUESTIONNAIRE

Study Title: *Evaluation of Different Test Condoms*

Today's Date: ___/___/___

ID Number: ___/___

General Information:

- How old are you? ___ years
- What is the highest grade that you have completed in school?

None	0					
Primary	1	2	3	4	5	6
Secondary	7	8	9	10	11	12
University	13	14	15	16	17+	

- What is your race?
 - Asian
 - Black
 - Hispanic
 - White
 - Other, specify _____

- How many condoms have you ever used during your LIFETIME?
 - Never used condoms → **SKIP TO FIRST CONDOM SECTION**

- Between 10 and 25
- Between 26 and 100
- More than 100

- How many condoms have you used in THE PAST YEAR?
 - Have not used condoms in the past year → **SKIP TO FIRST CONDOM SECTION**

- Between 10 and 25
- Between 26 and 100
- More than 100

- What type(s) of condoms have you used in THE PAST YEAR?
 - Natural skin
 - Latex
 - Both of the above

- Both of the above

- How many condoms have you had break in THE PAST YEAR?

___ (# of condoms)

___ (# of condoms)

COMPLETE THE FOLLOWING QUESTIONS IMMEDIATELY AFTER USING THE FIRST CONDOM

FIRST CONDOM

INSTRUCTIONS: PLEASE ANSWER EVERY QUESTION. Answer only for yourself, not your partner.

- Circle the color of the dot that appears on the condom package. (Your packet contains only two condoms)
 - Red
 - Blue
 - Yellow

- Were you able to use this condom?
 - Yes → **SKIP TO QUESTION 3**
 - No
If no, why weren't you able to use it?

SKIP TO FINAL INSTRUCTIONS AT END OF FIRST CONDOM SECTION

- How well did you like the condom?
 - Liked it very well
 - Liked it fairly well
 - Neutral/no opinion
 - Somewhat disliked it
 - Strongly disliked it
- How would you rank this condom based on the following characteristics? (CIRCLE THE BEST RESPONSE)

		<i>Below</i>			
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Overall design	1	2	3	4	5
Amount of lubricant	1	2	3	4	5
Ease in opening package	1	2	3	4	5

- How would you rank this condom in EACH of the following categories? (CIRCLE THE BEST RESPONSE)

		<i>Below</i>			
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Ease of putting on	1	2	3	4	5
Comfort of base of condom (open end)	1	2	3	4	5
Feeling of lubricant	1	2	3	4	5
Color of condom	1	2	3	4	5
Length of condom	1	2	3	4	5
Width of condom	1	2	3	4	5
Strength	1	2	3	4	5
Odor (smell)	1	2	3	4	5
Noise	1	2	3	4	5
General fit	1	2	3	4	5
Comfort in use	1	2	3	4	5
Sensitivity	1	2	3	4	5
General performance	1	2	3	4	5

ID Number: ___/___

6. What do you think of the design of this test condom? Please comment on the general **APPEARANCE** of this condom. If you have used other condoms in the past, please compare it to the other condoms you have used.

7. How did this test condom **FEEL** when you used it? If you have used other condoms in the past, please compare it to the other condoms you have used.

8. Did you have any problems putting on the condom?

0. No → **SKIP TO QUESTION 9**

1. Yes

If yes, what problems did you have?

(CIRCLE ALL THAT APPLY)

1. Package difficult to open
2. Lubricant made handling condom difficult
3. Condom did not slip onto penis easily
4. Condom was too short
5. Base (open end) of condom was too tight
6. Condom was too tight on penis
8. Other, specify _____

9. Did the condom cause you any irritation or discomfort?

0. No → **SKIP TO QUESTION 10**

1. Yes

If yes, what irritation or discomfort did the condom cause?

(CIRCLE ALL THAT APPLY)

1. Uncomfortable to put on
2. Condom was too long
3. Condom fit, but extra material at base of penis was noticeable
4. Condom pinched skin (tight at base)
5. Condom caught hair
6. Feel of the material was unpleasant
7. Condom smelled bad
8. Noise was unpleasant
9. Too much friction
10. Condom was too loose
11. Too little lubrication
88. Other, specify _____

10. Did the condom ever slip off?

0. No → **SKIP TO QUESTION 11**

1. Yes

If yes, **WHEN** did the condom slip off?

1. During sex
2. At the end of sex (during withdrawal)
9. Don't know

11. Did the condom break?

0. No → **STOP, COMPLETE NEXT PAGE IMMEDIATELY AFTER USING SECOND CONDOM**

1. Yes

If yes, **PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS.**

WHERE did the condom break?

1. At the tip (closed end of condom)
2. On the shaft (area between the tip and the base (open end) of the condom)
3. At the base (opening of the condom)
4. At the base (in the extra material around the opening of the condom)
9. Don't know

WHY did the condom break?

1. Condom ripped when opening package
2. Fingernail tore it
3. Carelessness/mishandling
4. Condom too dry
8. Other, specify _____
9. Don't know

IF YOU BREAK A CONDOM, OR THE CONDOM WAS UNUSABLE, PLEASE PLACE THE CLEANED CONDOM INSIDE THE ENCLOSED ZIPLOCK BAG AND COMPLETE THE NEXT PAGE IMMEDIATELY AFTER USING THE SECOND CONDOM

SECOND CONDOM

FEMALE QUESTIONNAIRE

INSTRUCTIONS: PLEASE ANSWER EVERY QUESTION. Answer only for yourself, not your partner.

Today's Date: ___/___/___

ID Number: ___/___

1. Circle the color of the dot that appears on the condom package. (*Your packet contains only two condoms*)
1. Red
 2. Blue
 3. Yellow

2. Were you able to use this condom?
1. Yes **→ SKIP TO QUESTION 3**
 2. No
If no, why weren't you able to use it?

SKIP TO FINAL INSTRUCTIONS AT END OF SECOND CONDOM SECTION

3. How well did you like the condom?
1. Liked it very well
 2. Liked it fairly well
 3. Neutral/no opinion
 4. Somewhat disliked it
 5. Strongly disliked it
4. How would you rank this condom based on the following characteristics? (**CIRCLE THE BEST RESPONSE**)

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Overall design	1	2	3	4	5
Amount of lubricant	1	2	3	4	5
Ease in opening package	1	2	3	4	5

5. How would you rank this condom in ***EACH*** of the following categories? (**CIRCLE THE BEST RESPONSE**)

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
General appearance	1	2	3	4	5
Ease of putting on	1	2	3	4	5
Comfort of base of condom (open end)	1	2	3	4	5
Feeling of lubricant	1	2	3	4	5
Color of condom	1	2	3	4	5
Length of condom	1	2	3	4	5
Width of condom	1	2	3	4	5

Question 5 continued.

	<i>Below</i>				
	<i>Excellent</i>	<i>Good</i>	<i>Average</i>	<i>Average</i>	<i>Poor</i>
Strength	1	2	3	4	5
Odor (smell)	1	2	3	4	5
Noise	1	2	3	4	5
General fit	1	2	3	4	5
Comfort in use	1	2	3	4	5
Sensitivity	1	2	3	4	5
General performance	1	2	3	4	5

6. What do you think of the design of this test condom? Please comment on the general ***APPEARANCE*** of this condom. If you have used other condoms in the past, please compare it to the other condoms you have used.
- _____
- _____

7. How did this test condom ***FEEL*** when you used it? If you have used other condoms in the past, please compare it to the other condoms you have used.
- _____
- _____

8. Did you have any problems putting on on the condom?
0. No **→ SKIP TO QUESTION 9**
 1. Yes

- If yes, what problems did you have?
(CIRCLE ALL THAT APPLY)
1. Package difficult to open
 2. Lubricant made handling condom difficult
 3. Condom did not slip onto penis easily
 4. Condom was too short
 5. Base (open end) of condom was too tight
 6. Condom was too tight on penis
 8. Other, specify
- _____

9. Did the condom cause you any irritation or discomfort?
0. No **→ SKIP TO QUESTION 10**
 1. Yes

- If yes, what irritation or discomfort did the condom cause?
(CIRCLE ALL THAT APPLY)
1. Uncomfortable to put on
 2. Condom was too long
 3. Condom fit, but extra material at base of penis was noticeable
 4. Condom pinched skin (tight at base)
 5. Condom caught hair
 6. Feel of the material was unpleasant
 7. Condom smelled bad
 8. Noise was unpleasant
 9. Too much friction
 10. Condom was too loose
 11. Too little lubrication
 88. Other, specify
- _____

ID Number: ___/___

10. Did the condom ever slip off?

0. No → SKIP TO QUESTION 11

1. Yes

If yes, WHEN did the condom slip off?

1. During sex
2. At the end of sex (during withdrawal)
9. Don't know

11. Did the condom break?

0. No → SKIP TO QUESTION 12

1. Yes

If yes, PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS.

WHERE did the condom break?

1. At the tip (closed end of condom)
2. On the shaft (area between the tip and the base (open end) of the condom)
3. At the base (opening of the condom)
4. At the base (in the extra material around the opening of the condom)
9. Don't know

WHY did the condom break?

1. Condom ripped when opening package
2. Fingernail tore it
3. Carelessness/mishandling
4. Condom too dry
8. Other, specify _____
9. Don't know

Comparison of the two test condoms:

12. Were the two test condoms different?

0. No → SKIP TO QUESTION 15

1. Yes

13. What do you think was/were the difference(s) between the two condoms that you tested?

(CIRCLE ALL THAT APPLY)

1. The condoms were different in size (length, width)
2. The condoms were shaped differently
3. The condoms were made of different materials
4. The condoms were of different thicknesses
8. Other, specify _____

9. Don't know

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2. Possibly
3. Not sure
4. Probably not
5. No
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