

# **A Randomized Crossover Trial of the Functional Performance, Safety and Acceptability of the Origami Internal Condom.**

## **Study Report Version 1.0**

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## Executive Summary

**Introduction:** Condoms are a proven effective barrier method and when used consistently and correctly, both male and female condoms (FCs) protect against pregnancy and sexually transmitted infections (STIs), including HIV. To date, no male or female condom has been designed, tested, reviewed or approved by the FDA to use for anal intercourse, a leading source of HIV transmission. An internal condom (IC) that could be used vaginally and/or anally could present a viable alternative to the standard male latex rolled condom and female condom. In addition, there is a need to address sensitivity and pleasure that have potential to address a broad range of user complaints, personal preferences and could increase condom uptake on a global scale.

Unlike the traditional rolled male condom the proposed IC is based on tactile, 'direct sensation' created with penile movement against the condom's internally lubricated surface to mimic the natural fluid environment of human sexual anatomy. The proposed IC reconsiders the condom as a shared-experience device rather than defined as a gender-specific 'male' or 'female' condom type. Additionally, the design is primarily based on improved pleasure – to optimize pleasure for each partner, provide protection (contraception and HIV/STI prevention), and simultaneously to improve safety and intimacy.

**Purpose:** To evaluate functional performance, safety and acceptability of the Origami internal condom. Results of this trial will be used for finalization of product attributes.

**Study design:** Randomized comparative cross-over trial to evaluate functional performance, safety and acceptability of the internal condom compared to FC2.

**Sample:** The study enrolled 28 couples (14 heterosexual for vaginal use and 14 homosexual for anal use) agreeing to use 5 each of the 2 condom types. The target population was urban, sexually-active couples who are experienced users of MCs.

**Objectives:** Primary- To determine functional performance and acceptability of each of two internal condom types. Secondary- To gather safety data (as determined by the number of adverse events) on each of the condom types.

**Results:** The study enrolled 14 heterosexual women, 13 of which completed both follow up visits. N=11 male partners of the female participants completed a follow up survey, after using both condom types with their partner. A total of 28 homosexual men were enrolled in the study of which 26 completed the first follow up visit and 25 completed both follow up visits.

**Heterosexual couples:** In total, 130 condom packets were opened and 130 condoms were used by heterosexual couples. No clinical breakage was recorded in both condom types. No invagination and slippage were reported for the FC2. Rates of invagination and misdirection were 7.7% and slippage was 9.2% for the Origami condom.

**Homosexual couples:** In total, 130 condom packets were opened and 130 condoms were used by homosexual couples. Both condom types had zero non-clinical breakage. The Origami condom clinical breakage rate was 3.1% compared to 1.5% for the FC2. No invagination occurred for the Origami condom compared to 4.6% for FC2. The misdirection rate was 9.2% for both condom types. The slippage rate for the Origami condom was lower (15.4%) than FC2 (18.5%).

The total condom failure was slightly lower in the homosexual couples (27.7%) for Origami compared to the FC2 (33.8%). For heterosexual couples failure rates were lower overall for both condom types. For FC2 total condom failure was 7.7% compared to Origami (24.6%).

Eight of the 11 male heterosexual participants liked the Origami condom the best overall; two of the 11 preferred the FC2 and one did not like either condom. The majority (11/13) of the female heterosexual participants liked the FC2 condom best. One liked the Origami condom best and another liked both

condom types the same. Of the 25 homosexual male participants, just over half (14/25) liked the FC2 best, compared to (9/25) who liked the Origami condom best. Two liked both condom types the same.

Few safety issues were report overall. For FC2 six events were recorded and 5 episodes of pain were reported by one woman for FC2 and were of short duration (20 mins). Four events were reported for Origami and only one lasted longer than one hour.

**Conclusion:**

Functionality was found to be similar between FC2 and Origami in the homosexual couples. Generally the condom failure rates in homosexual couples was higher than seen in vaginal sex for FC2 in this study and other female condom functionality studies and this may be related to the use of the FC2 for anal sex. The ring was removed before FC2 use in homosexual couples. This is always recommended as it may cause pain in the anus. However this may make the condom less stable in the anus. The rates of FC2 failure in heterosexual couples are similar to those seen in other studies, however the rates of failure for the Origami were higher. This may be related to the mode of insertion which is on the male partner's penis, which is required as there is no insertion component (ring/sponge) in the Origami condom.

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## LIST OF ACRONYMS

<b>AE</b>	<b>Adverse Experience or Adverse Event</b>
<b>DLGCHC</b>	<b>Durban Lesbian and Gay Community Health Centre</b>
<b>FC</b>	<b>Female Condom</b>
<b>FP</b>	<b>Family Planning</b>
<b>HIV</b>	<b>Human Immunodeficiency Virus</b>
<b>HREC</b>	<b>Human Research Ethics Committee</b>
<b>IC</b>	<b>Internal Condom</b>
<b>MatCH Research</b>	<b>Maternal, Adolescent and Child Health Research Unit</b>
<b>MC</b>	<b>Male Condom</b>
<b>NRL</b>	<b>Natural Rubber Latex</b>
<b>SAE</b>	<b>Serious Adverse Event</b>
<b>STI</b>	<b>Sexually Transmitted Infection</b>

# 1.0 INTRODUCTION

## 1.1 Background

Condoms are a proven effective barrier method and when used consistently and correctly, both male and female condoms (FCs) protect against pregnancy and sexually transmitted infections (STIs), including HIV [1]. Yet inconsistent and incorrect use, decrease in pleasure and spontaneity, and likelihood that condoms are discontinued in longer-term heterosexual and homosexual partnerships are some of the challenges impeding the condoms' success in the fight against STIs and HIV [2-8]. To date, no male or female condom has been designed, tested, reviewed or approved by the FDA to use for anal intercourse, a leading source of HIV transmission. Observational studies in the U.S. indicate that some men who have sex with men use FCs [9-12]. A cross sectional survey among male clients attending services at a Gay Men's Health Crisis in New York City found that the prevalence of ever FC use for anal intercourse was 17%, and 14% reported having done so in the past six months. Moreover, some men reported using the FC for anal sex with female partners [12].

FCs are now available in synthetic latex and latex designs [13]. The currently available USFDA approved FC2 FC made of synthetic latex has replaced the more expensive polyurethane FC of the same design. Although not FDA approved, the Cupid FC made of natural rubber latex (NRL) was prequalified in 2012 by UNFPA/WHO for public sector donor procurement.

The basic process used to manufacture NRL condoms has not changed significantly over the last 20 years although quality of products has improved [14]. Material science has undergone revolutionary transformation in the last decade yet that knowledge has not been applied to improve the product attributes of condoms.

## 1.2 Rationale

An internal condom (IC) that could be used vaginally and/or anally made of an adapted latex material could present a viable alternative to the standard male latex rolled condom and female condom. Reduced sensation and diminished performance/pleasure have become unchallenged consumer compromises for over 100 years, perpetuating negative consumer perceptions and inconsistent condom compliance. In addition, absent from condom technology, is the need to address sensitivity and pleasure that have potential to address a broad range of user complaints, personal preferences and could increase condom uptake on a global scale.

Unlike the traditional rolled male condom the proposed IC is based on tactile, 'direct sensation' created with penile movement against the condom's internally lubricated surface to mimic the natural fluid environment of human sexual anatomy. The proposed IC reconsiders the condom as a shared-experience device rather than defined as a gender-specific 'male' or 'female' condom type. Additionally, the design is primarily based on improved pleasure – to optimize pleasure for each partner, provide protection (contraception and HIV/STI prevention), and simultaneously to improve safety and intimacy.

Latex condoms cause allergies in a small proportion of individuals. The alternative synthetic products may be safer but for most resource poor countries they are an unaffordable option. According to the Centers for Disease Control and Prevention, proteins in latex cause a range of allergic reactions.[15] Natural rubber latex contains over 200 proteins, similar to other natural plant materials, of which 13 are known allergens. The condom prototypes used in this study address the issue of safety by using Vytex NRL which is created through a process that significantly reduces these proteins [16].

This randomized crossover trial, investigating the functional performance, safety and acceptability of the Origami IC was conducted in central Durban, South Africa in two groups of participants: 1) female clients of Commercial City Clinic and their male partners, and 2) male clients and their male partners of the Lesbian and Gay Community and Health Centre (DLGCHC).

The Commercial City Clinic is a busy sexual and reproductive health facility which sees over 8000 clients per month. The DLGCHC is a community drop-in centre providing a range of support groups and HIV counseling and testing services (HCT), STI and TB screening and treatment referrals. South Africa was selected because of the high acceptance of the MC and FC within the population and the recognition by the South African Department of Health of the importance of condoms as a means of protection against pregnancy and HIV/STIs.

## 2. Study objectives and endpoints

### 2.1 Primary Objectives

The primary objectives of this study were to compare the functional performance and acceptability of the two internal condom types (Origami IC and FC2 FC) within the selected study population.

### 2.2 Primary Objective End Points

**2.2.1 Functionality:** The internal condom was used as an FC i.e. it was inserted in both cases. It was not used as an MC in the case of the homosexual couples, hence the functional performance definitions for FCs were used. In addition the control condom- the FC2, uses these definitions.

For each condom type, the proportion of functional performance events was calculated. Primary analyses centered on total clinical failure and total female condom failure. In addition, rates of clinical breakage, total breakage, slippage, misdirection, and invagination were calculated.

The following definition of terms have been approved by the Female Condom Technical Review Committee Meeting at the WHO in Geneva, Switzerland, for use in FC studies. [17] These definitions were used in the analysis of the internal condom function data.\* While multiple failures may be experienced with a single device within one sexual act, failures under this condition were counted as a single event for data analysis purposes. [Note: Male latex condom failures are counted in this manner.]

- **Clinical breakage** is defined as breakage during sexual intercourse or during withdrawal of the female condom from the vagina. Clinical breakage is breakage with potential adverse clinical consequences. The **clinical breakage rate** is calculated by dividing the number of female condoms reported to have broken during sexual intercourse or during withdrawal by the number of female condoms used during sexual intercourse.
- **Total breakage** is defined as the sum of all female condom breakages at any time before, during or after sexual intercourse. It includes both clinical breakages and non-clinical breakages. The **total breakage rate** is calculated by dividing the total number of female condoms that broke by the number of female condom packages opened.
- **Slippage** is defined as an instance when a female condom slips completely out of the vagina during sexual intercourse. The **slippage rate** is calculated by dividing the number of female condoms that slipped by the number of female condoms used during sexual intercourse.
- **Misdirection** is defined as vaginal penetration whereby the penis is inserted between the female condom and the vaginal wall. The **misdirection rate** is calculated by dividing the number of reported events of misdirection by the number of female condoms used during sexual intercourse.
- **Invagination** is defined as an instance when the external retention feature of the female condom is partially or fully pushed into the vagina during sexual intercourse. The **invagination rate** is

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\* These definitions refer to FCs however if condoms used for anal sex are named as internal condoms, terminology would need to address this issue.



calculated by dividing the number of events of invagination by the number of female condoms used during sexual intercourse.

- **Total clinical failure** is defined as the sum of female condoms that clinically break or slip, or are associated with misdirection, invagination or any additional failure modes(s) identified in the risk assessment which results in the reduction of the female condom protective function. The **total clinical failure rate** is calculated by dividing the number of female condoms with a clinical failure by the number of female condoms used during sexual intercourse.
- **Total female condom failure** is defined as a female condom for which a non-clinical breakage, clinical breakage or slippage occurs, or is associated with misdirection, invagination or any additional failure modes(s) identified in the risk assessment. The **female condom failure rate** is calculated by dividing the number of female condoms that fail by the number of female condom packages opened.

**2.2.2 Acceptability:** Frequency of key acceptability endpoints were calculated and include: comfort in use; ease of insertion and removal; like or dislike of product attributes (e.g. material, pleasure, fit,); and adequacy and feel of lubrication.

## 2.3 Secondary Objective

The secondary objective was to compare the safety of the two condom types.

### 2.3.1 Secondary Objective End Points

**Safety:** Proportion of participants with symptoms of and proportion of FC2/Origami IC uses with reports of genitourinary irritation or anal irritation during or immediately after any of the 5 separate uses were calculated for each condom type. Medical and serious adverse events were classified by relatedness, expectedness and severity.

## 3. Ethics review and approvals

All documents related to this study were reviewed and approved by the Human Research Ethics Committee of the University of Witwatersrand, Johannesburg, South Africa, prior to study initiation and enrolment of participants (HREC approval #M150149). All participating organizations gave approval for the research conducted at their sites. The consent process and all checklists, condom use logs and surveys used in the study were written and conducted in a language understandable to the participants. All relevant documents were translated into isiZulu. Written informed consent was obtained from all study participants prior to their enrolment in the study.

## 4. STUDY PROCEDURE

### 4.1 STUDY PRODUCTS AND TREATMENTS

#### 4.1.1 FC2 FC

The FC2 (see Figure 1) is a second-generation female condom manufactured by the Female Health Company (Chicago, IL). The FC2 has WHO/UNFPA and US FDA approval and has been granted the CE Mark of the European Union.



Figure 1: The FC2 Female Condom

The device is made from a synthetic polymer (nitrile) film. The condom is designed as a loose-fitting pouch that lines the vagina (or anus if used for anal sex). It has two flexible rings. The outer ring at the open end is rolled from the nitrile material. The outer ring remains outside the vagina/anus and covers the external genitalia during intercourse. An internal polyurethane ring is removable and serves as the insertion mechanism and anchors the device within the vagina. Retrospective reports indicate the ring is normally removed for anal sex. [9-12] FC2 measures 180mm in length and 80mm in lay-flat width. The device is pre-lubricated with dimethicone.

#### 4.1.2 Origami IC

The Origami IC (Figure 2) is made of Vytex® Natural Rubber Latex (NRL), a modified NRL product. In May 2009 the U.S. Food and Drug Administration granted 510(k) clearance to market and sell a condom made with Vytex that contains less than 2 µg/dm<sup>2</sup> of antigenic proteins [18].

Vytex Natural Rubber Latex (NRL) is a brand of natural rubber latex produced and marketed by Vystar Corporation. Vytex NRL is an alternative material to petroleum-based synthetics and traditional, or Hevea, natural rubber latex. Protein test results show that Vytex NRL typically has 90% fewer antigenic proteins than Hevea natural rubber latex.[18]

Physical properties of Vytex include barrier protection, elasticity, tactile sensitivity, strength, comfort and fit. Vytex comes in two grades: Vytex high ammonia (Vytex HA) for surgical, exam and rubber gloves, condoms, catheters and balloons, and Vytex low ammonia (Vytex LA) for adhesive and foam applications.

Vytex NRL's advantage over other standard NRL varieties is that it maintains all the attributes of latex while typically containing 90 percent fewer allergy-causing proteins. This is achieved with only a slight increase in raw material cost compared to NRL and well below the material costs of most synthetic petroleum-based alternatives. The reduction in antigenic properties is introduced into the normal latex manufacturing process.

This key reduction in allergenic proteins is achieved without losing the properties that give NRL its advantages over synthetic substitutes: superior barrier protection, strength, elasticity, memory, skin-like comfort and tactile sensitivity. Vytex NRL also has the advantage of being virtually odor-free due to the removal of proteins. Vytex NRL is 100% natural, renewable and biodegradable.

The outer sheild of the IC remains outside the vagina/anus and partly covers the external vaginal genitalia/anus during intercourse. The fluted design serves as the insertion mechanism and anchors the device within the vagina/anus. The IC measures 178 mm in length and 38mm in lay-flat width.

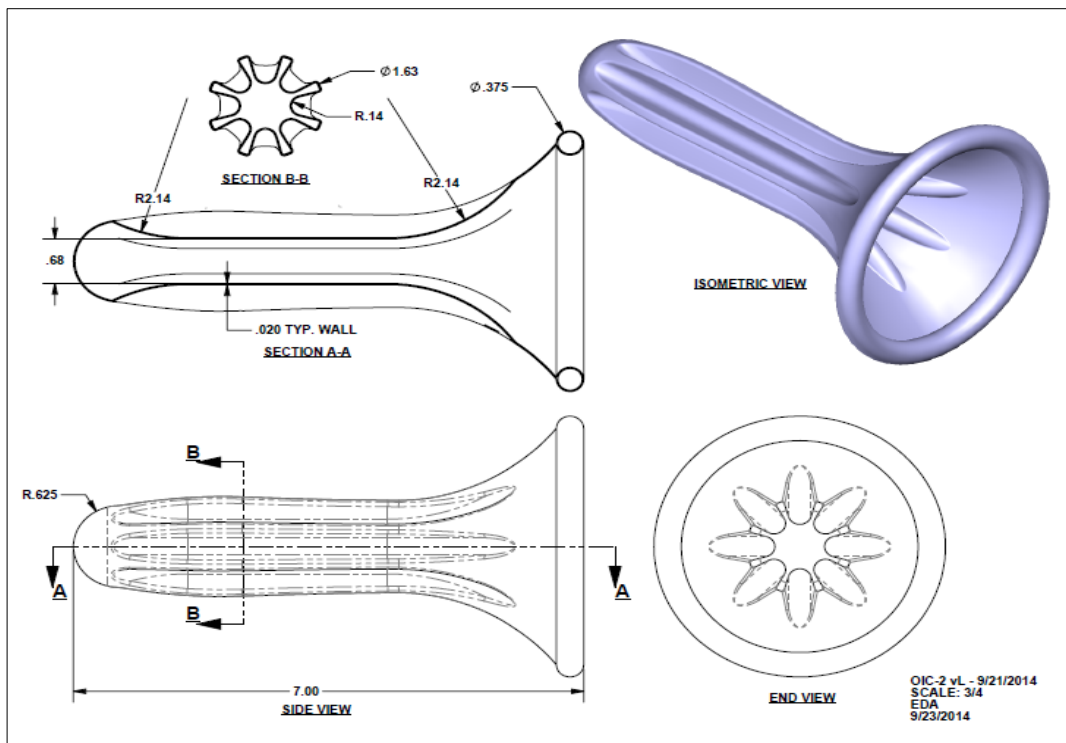


Figure 2: The Origami Internal Condom

All IC condoms tested in this trial were non-lubricated. “WET” lubricant was offered and supplied to participants to meet their individual preferences. The brand “WET”, a popular silicone based lubricant is available to purchase online from “Adult World” South Africa, an adult lingerie and lifestyle products company.

**4.2 Pregnancy Test:** The clinic standard of care (urine pregnancy test) was used to determine pregnancy status in women. The pregnancy test has a sensitivity of 50mIU/mL so as to detect pregnancies on/around the day of the expected missed period.

**4.3 STI Therapy:** If required, appropriate treatment was supplied free of charge for treating incident STIs. The clinical standard of care for treatment was used.

#### 4.4 Labeling and Packaging of Products and Materials

The Origami ICs were provided in plastic containers and the packaging displayed the manufacturer’s name, lot/batch number and date of expiry. The FC2 FC was provided in its standard commercial packaging available in South Africa. Both condom types were further labeled with the following information:

##### RESEARCH CONDOM

##### CAUTION:

##### Limited by law to investigational use.

This product is for research purposes only and must not be distributed or sold.

This product may fail during use and must not be relied upon for contraception or sexually transmitted disease prevention.

**This product contains natural rubber latex which may cause allergic reactions\*.**

\*This sentence was removed for the FC2, which is synthetic nitrile and does not contain NRL.

Over the course of this research study, the participants received two study packets, one for each type of condom to be used (Origami IC and FC2 FC). The packets were distributed to each participant as determined by the participant randomization sequence. The contents of the packets included:

- 5 condoms (either Origami IC or FC2 FC)
- “WET” lubricant, as required
- 1 Manufacturer’s Use Instruction Sheet per condom type
- 1 Condom Use Log (with next appointment noted on Log),
- Black ballpoint pen

## **5. RESEARCH STUDY DESIGN**

This research study was a two-period, crossover randomized trial to compare the functional performance, acceptability and safety of the Origami IC to the control FC2 FC.

The consent process and all checklists, condom use logs and surveys used in the study were written and conducted in a language understandable to the participant. At enrollment, baseline data was gathered on participant demographics and past male and female condom use.

Enrolled participants were asked to use 5 devices of each type of condom (Origami IC and FC2 FC). They were asked to return to the clinic for a follow-up visit after using each type of device. Data on device function, acceptability and safety for each condom type were collected during follow-up visits.

Screening/enrollment visit: Clients at each site were told about the study. If they expressed interest in participating, they were given the study information sheet.

At the DLGCHC interested men were asked to read the information sheet and to take it home to their partners as it described the study requirements and the couple’s potential role in the study. If they agreed to participate, they were asked to contact the study staff at the site to make an appointment for consent and screening. The couple were asked to provide individual written consent.

At Commercial City Clinic, the woman were given the information sheet and were enrolled without the male partner, if eligible. The male partner was asked if he would be willing to attend a follow-up interview on completion of use of both study condom types.

Before enrolment, the male couples at the DLGCHC and the women at Commercial City Clinic were pre-screened for visible STIs using the syndromic diagnostic tool and female participants at Commercial City Clinic underwent a pregnancy test to determine pregnancy status. Further, they were administered the selection criteria checklist to determine whether they met the remaining study inclusion criteria. Twenty-eight couples were enrolled in the study.

To minimize use-order effects, the couples were randomized to condom-type use order. Concealment of the random allocation was accomplished through use of sequentially numbered envelopes. After revealing the appropriate condom type, the randomization slip was placed in a protective envelope and filed with the participant’s other study documents.

During the enrollment visit, study staff administered a baseline survey to collect demographic information. Using a demonstration model, the study staff demonstrated condom use (IC or FC2) and trained the participants in the proper use of their first assigned condom. Further, they were provided with instructions on how to complete the condom use log. The participants were given their first study packet which contained 5 condoms of their assigned type along with a condom use log, written instructions for using the condoms and “WET” lubricant as required.

The male couples were instructed to remove the ring from the FC2 as per documented reports of discomfort and adverse events [19-21].

The participants were instructed to use the condoms during 5 acts of vaginal/anal intercourse and to complete the condom use log after use of each condom. For male couples, one man of the couple inserted the IC/FC for all 5 uses (the receptive partner). This was discussed with the male couple and they were asked to choose the index receptive participant. This was to ensure that feedback was consistent from one partner for 5 condom uses either as the insertive or receptive partner.

Core questions were asked of all participants but the partner that inserted the condom (female in the heterosexual couple and male receptive partner in the homosexual couple) were able to respond to questions particular to comfort of insertion and use of the condoms.

In a previous study (unpublished) a relationship was found between the condoms pulling out and a larger penis girth. To explore this, men participating in the study were asked to measure the length and girth of their penis using a penis measurement kit with the aim to determine potential relationships between penis size (length/girth) and condoms being pushed in or pulled out of the vagina/anus.

The measuring kit consisted of two 1/4" strips of paper: 1) yellow=12" length and 2) green= 8" length were used. The kit included a card with simple instructions and the 2 strips laced through the card. Male participants were asked to wrap the green strip around the erect penis for the girth and tear it off. The yellow strip was used to measure penis length. The paper strips had no increments marked on them. They were collected at the exit visit.

Couples did not have to use the condoms during consecutive acts of intercourse. Once they used all 5 condoms in the study packet, they were asked to return to the clinic for a follow-up visit. Couples attended together but were interviewed separately or they booked appointments at different times if more convenient. The first follow-up visit occurred approximately one month after enrollment and was pre-scheduled. The date of the first follow-up visit was written in the designated location on the condom use log. Participants who completed using their condoms prior to their scheduled follow-up visit, were encouraged to call the clinic to re-schedule their follow-up visit. Women and men enrolled in the study were paid R100 (~US\$10.0) for their time and travel expenses associated with the enrollment and follow up visits.

Follow-up visits: There were two follow-up visits—one after use of each type of condom and they were instructed to return to the clinic after use of each condom type.

During the follow-up visits, study staff reviewed the information on the condom use logs for completeness and accuracy. Further, the participants were administered a follow-up survey about their experiences using the condoms.

After the first follow-up visit participants obtained their next condom packet in their assigned use sequence. They were trained in the use of the 2<sup>nd</sup> condom type, were given appropriate written condom use instructions, and their next follow-up visit was scheduled.

During the second follow-up visit, study staff reviewed the information on the condom use log for completeness and accuracy. The discontinuation form was completed and the participants were reimbursed. Participation period for participants lasted 2-3 months.

## **5.1 Participant Recruitment and Screening Procedures**

Couples volunteering for this study were recruited from two sites in Durban, South Africa.

### **5.1.1. Heterosexual Couples**

The heterosexual couples were recruited from the Commercial City Clinic. Women were informed about the study through a group talk by the study nurse addressing all the clients waiting for their consultations. They were informed of the study and if interested, took an information leaflet to read

themselves and for their partner to read. The information sheet informed the couple of the eligibility criteria required to participate.

If interested the woman was asked to come to the study office where she was given more information and was asked if she wished to volunteer. If yes, she was asked to provide written informed consent prior to screening. She was told that we were also interested in conducting one follow-up interview with her partner and we asked if she was willing to ask her partner if he would participate. Those who were willing were given an information sheet to give to their partners which explained his role in the study. Male partner non-participation was not an exclusion criteria for the woman's participation.

### 5.1.2 Homosexual Couples

For the male couples, we sought volunteers from the DLGCHC, willing to be recruited as a couple as there is less information on male couples and their use of FCs together. Men were informed about the study through a group talk by the study nurse addressing all the clients waiting for their group discussions/support group meetings in the general waiting area. One of the group meeting leaders also introduced the study in their various workshops and meetings. They informed the men that the study was recruiting couples and if interested they could take an information leaflet to read themselves and take home for their partner to read. The information sheet informed the couple of the eligibility criteria required to participate.

If interested, men were asked to come into the DLGCHC where they were given more information and were asked if they wished to volunteer. The men could choose to come to the centre together or individually depending on their availability. If they agreed to participation they were asked to provide written informed consent prior to screening.

As the homosexual couple used the condoms for anal sex we asked that one man in the couple take on the role of receptive partner i.e. he was the one who had the condom placed inside the anus when they were used each time (for the duration of the study). The partner that did not have the condom inserted was asked to give feedback on experience in use with his partner.

The eligibility criteria differed between the couples at each site:

#### 5.1.3 Eligibility criteria for both men and women:

- be between the ages of 18 and 45 years (inclusive)- women; 18 and 55 years (inclusive)- men
- 1) literate (able to read a newspaper or letter easily);
- 2) sexually active (at least two vaginal/anal coital acts per week and not abstinent in the month prior to enrollment);
- 3) experience of MC use;
- 4) in an exclusive (monogamous) sexual relationship while participating in this research study;
- 5) in a sexual relationship with this partner for at least 6 months;
- 6) must not be a sex worker;
- 7) must be without observable evidence of STI as determined through syndromic diagnosis and vaginal/penile/anal examination;
- 8) no known sensitivities or allergies to latex, polyurethane, vaginal/sexual lubricants or the lubricants used on condoms;
- 9) willing to give informed consent;
- 10) able to complete the condom use logs;
- 11) willing to adhere to the follow-up schedule and all study procedures;
- 12) willing to provide research study staff with an identity number, address, phone number or other locator information while participating in the study; and,
- 13) willing to participate in the study for up to four months.

#### **5.1.4 Eligibility criteria for women only:**

- 14) must not be pregnant (as determined by pregnancy testing) or planning a pregnancy during the time of the research study;
- 15) using hormonal or other non-barrier contraception (e.g. OCs, injectables, IUD, or have had a tubal sterilization);
- 16) must not be menopausal (defined as 12 months without menstruation); and,
- 17) willing to have fingerprint scan to check for co-enrollment in other research projects.

## **5.2 Randomization, Allocation Concealment and Blinding**

Participants were randomized to condom use order. In heterosexual couples, if the male partner did not participate only the female partner was randomized. Balance was maintained across sequences (i.e. equal numbers of couples randomized to each of the two sequences) using block randomization. A statistician (not otherwise involved in this study) developed the random allocation sequence using a validated statistical program in Stata (StataCorp LP, College Station, Texas, USA). [22]

Use-order assignments consisted of separate, sequentially numbered, envelopes. Trained staff opened the envelopes to reveal the first condom type only after the participants qualified for study inclusion and were properly enrolled.

Data managers and analysts were blinded until all data were captured and the primary analysis programs verified. Likewise, all reasonable attempts were made to keep other staff blinded until the primary analysis programs were verified. These efforts included masking condom use sequence variables in datasets provided to data managers and the project leaders. The statistician analyzing the data was not blinded. Due to dissimilarities of the study products, it was not possible to blind participants and clinic staff associated with the project.

## **6. DATA**

Data was captured on data collection forms (DCFs) and take-home condom use logs. Questionnaires were interviewer-assisted and the condom use logs were completed at home by the participants. At each follow-up visit, clinic staff reviewed the information from the condom use log with the participant to assess correctness and completeness.

Data from the DCFs were entered into the Epidata Entry Client Version 2.0.5.17 database system. Responses to open-ended questions were translated into English and coded prior to data entry. The data were entered by experienced data capturers. Any inconsistencies were resolved with the help of the data manager or principal investigators. The database was backed up on a daily basis.

### **6.1 Hypothesis for the Primary Endpoint and Study Size Justification**

This was a pilot study to further develop and refine the IC condom prototype and therefore the sample size was not large enough to indicate statistically significant differences between the two devices in device function, acceptability and safety. Rather the objectives were to get feedback on the subtle differences in the designs in terms of sensation and user experience, including ease of insertion.

For acceptability, scores ranging from 1 (lowest) to 5 (highest) will be compared across condom types using the Friedman test.

### **6.2 Data Analysis**

All analyses for primary and secondary endpoints were performed according to the assigned condom use sequence among the subset of participants who provided relevant follow-up data on at least one condom of each type.

### Condom Function

The failure rates, or proportions of condom uses with clinical breakage, total breakage, invagination, misdirection, slippage, total clinical failure were summarized by condom type according to endpoint definitions in **Section 2.2.1**.

### Safety Data

The proportion of participants with symptoms of genitourinary/anal/penile irritation during or immediately after any of the 5 separate uses were reported for each condom type.

Medical and serious adverse events, classified by relatedness to condom type, expectedness and severity were reported by condom type.

### Product Acceptability

The key acceptability endpoints (listed below) were summarized by condom type. For preference, a categorical endpoint, frequencies and percentages were calculated.

Key acceptability endpoints:

- comfort in use;
- enjoyment of/effect on sexual experience
- ease of insertion and removal;
- like or dislike of product attributes (e.g. material);
- and adequacy and feel of lubrication.

## **7. Results**

### **7.1 Enrollment and loss to follow up**

A total of 14 women were recruited and screened from the client population of the Commercial City Clinic and a total of 28 men were recruited and screened from the client population of the Durban Lesbian and Gay Community Health Centre. Fieldwork commenced in August 2015 and was completed in January 2016.

The study enrolled 14 heterosexual women who completed the baseline survey, and 13 of which completed both follow up visits. The loss to follow-up is 8% (i.e. 92% of the sample provided follow-up data on at least one condom of each type). N=11 male partners of the female participants completed a follow up survey, after using both condom types with their partner.

28 homosexual men were enrolled in the study and completed the baseline survey. N=26 completed the first follow up visit and N=25 completed both follow up visits. The loss to follow-up is 11% (i.e. 89% of the sample provided follow-up data on at least one condom of each type).

### **7.2 Demographics**

Table 1 provides the demographic characteristics of the study population. A total of 14 black females completed the baseline survey. They were on average 28.3 years of age with over half completing grade 12 schooling. Half of the female sample were unemployed and had one living child and reported relationship duration between one and five years. The majority were not married and did not live with their partners.

The average age of the 28 black males who completed the baseline survey was 28.6 years. Most had completed grade 12 schooling. The majority reported being students and the next highest report of being unemployed. Most were not married and did not live with their partners and over half of the sample had been in a relationship with their partners for less than a year.



**Table 1: Demographic Characteristics**

Demographic variable	Heterosexual Females	Homosexual Males
<b>N</b>	14	28
<b>Age</b> Mean (min, max)	28.3 (20, 43)	28.6 (19, 42)
<b>Group most identify with</b> n		
<i>Black</i>	14	28
<b>No. of years of school (grades) completed</b>		
10	2	1
11	4	1
12	8	26
<b>Primary occupation</b> n	7	5
<i>Unemployed</i>	2	-
<i>Self-employed</i>	2	3
<i>Unskilled labour</i>	2	2
<i>Office/sales</i>	1	7
<i>Student</i>	-	3
<i>Health/medical</i>	-	4
<i>Public service/Government/technical</i>	-	4
<i>Other</i>		
<b>No. of living children</b>		
1	7	n/a
2	5	n/a
3	1	n/a
4	1	n/a
<b>Relationship with current spouse/partner</b>		
<i>Married and living together</i>	1	-
<i>Married and not living together</i>	1	1
<i>Not married and living together</i>	1	7
<i>Not married and not living together</i>	11	19
<i>Other</i>	-	1
<b>Relationship duration</b>		
<i>Less than 1 year</i>	-	15
<i>1-5 years</i>	7	10
<i>6-10 years</i>	4	2
<i>More than 10 years</i>	3	1

Table 2 shows the reproductive characteristics of the sample. Most females and males reported MC use at last vaginal/anal sex act. Half of the female sample reported using MCs half the time during sex in the last six months compared to more males who used MCs every time. Most of the females had ever used a FC compared to the male sample and of these, none had used FCs at last sex. During sex in the past six months, majority of the females used FCs less than half the time and less than half of males used FCs half of the time. Half of the female sample had ever used tampons. Few participants reported having ever douched or placed medicine inside their vagina/anus. Less than half the female sample had ever used personal or sexual lubricant compared to most of the male sample who had. In the past six months, half the female sample used personal or sexual lubricant less than half the time compared to more males who used it every time during sex.

**Table 2: Sexual and Reproductive Health Status**

Variable	Heterosexual Females N=14	Homosexual Males N=28
<b>MC use at last vaginal/anal sex act n</b>		
No	3	4
Yes	11	24
<b>Frequency of MC use in the past 6 months n</b>		
<i>Less than half the time</i>	1	2
<i>Half the time</i>	7	1
<i>More than half the time</i>	1	4
<i>Every time</i>	2	17
<b>Ever used a FC n</b>		
No	5	21
Yes	9	7
<b>FC use at last vaginal/anal sex act n</b>		
No	9	7
<b>Frequency of FC use in the past 6 months n</b>		
<i>Never</i>	2	2
<i>Less than half the time</i>	6	1
<i>Half the time</i>	1	3
<i>More than half the time</i>	-	1
<b>Ever used tampons n</b>		
No	7	n/a
Yes	7	n/a
<b>Ever douched or placed medicine inside your vagina/anus n</b>		
No	13	21
Yes	1	7
<b>Ever used personal or sexual lubricant n</b>		
No	8	1
Yes	6	27
<b>Frequency of personal or sexual lubricant use during sex in the past 6 months n</b>		
<i>Never</i>	1	-
<i>Less than half the time</i>	3	1
<i>Half the time</i>	2	5
<i>More than half the time</i>	-	4
<i>Every time</i>	-	17

## 7.3 Functionality

Table 3 and 4 shows the number of condoms used, the number of failures of each type and the failure percentage (mean failure) by condom type.

**Table 3: Functionality: Heterosexual Couples**

Condom function	Condom type	Condoms N	Mean failure N=13 (%) N
Non-clinical breakage	Origami	65	(0) 0
	FC2	65	(0) 0
Clinical breakage	Origami	65	(0) 0
	FC2	65	(0) 0
Invagination	Origami	65	(7.7) 5
	FC2	65	(0) 0
Misdirection	Origami	65	(7.7) 5
	FC2	65	(7.7) 5
Slippage	Origami	65	(9.2) 6
	FC2	65	(0) 0
Total clinical failure*	Origami	65	20 (13)
	FC2	65	(7.7) 5
Total female condom failure	Origami	65	24.6 (16)
	FC2	65	(7.7) 5

\*3 condoms experienced 2 failures which are considered as one condom failure for total clinical failure

In total, 130 condom packets were opened and 130 female condoms were used by heterosexual women in this study to comparatively evaluate the Origami condom with the reference condom, FC2. No non-clinical breakage was recorded for either condom type. No invagination and slippage were reported for the FC2 condom. In terms of the Origami condom- rates of invagination and misdirection were 7.7% and slippage was 9.2%.

**Table 4: Functionality: Homosexual Couples**

Condom function	Condom type	Condoms N	Mean failure N=13 (%) N
Non-clinical breakage	Origami	65	(0) 0
	FC2	65	(0) 0
Clinical breakage	Origami	65	(3.1) 2
	FC2	65	(1.5) 1
Invagination	Origami	65	(0) 0
	FC2	65	(4.6) 3
Misdirection	Origami	65	(9.2) 6
	FC2	65	(9.2) 6
Slippage	Origami	65	(15.4) 10
	FC2	65	(18.5) 12
Total clinical failure*	Origami	65	(26.2) 17
	FC2	65	(32.3) 21
Total female condom failure	Origami	65	(27.7) 18
	FC2	65	(33.8) 22

\*2 condoms experienced 2 failures which are considered as one condom failure for total clinical failure

In total, 130 condom packets were opened and 130 female condoms were used by homosexual men in this study to comparatively evaluate the Origami condom with the reference condom, FC2.

Both condom types had zero non-clinical breakage. The Origami condom clinical breakage rate was 3.1% compared to 1.5% for the FC2 condom. No invagination occurred for the Origami condom compared to 4.6% for FC2. The misdirection rate was 9.2% for both condom types. The slippage rate for the Origami condom was lower (15.4) than FC2 (18.5%).

## 7.4 Lubrication

Table 5 shows lubrication use with both condom types for women and homosexual men.

Two women used the study lubricant for the FC2 condom- one on the penis before intercourse and one on the outside of the condom before intercourse. All women used the study lubricant for the Origami condom (100%). Two women reported using another non-study lubricant (3.1%) with the FC2 condom; and one woman used another non-study lubricant (1.5%) with the Origami condom. Other lubricants used included "Vaseline" and "Mosaic".

Less than half of the homosexual males used the study lubricant for the FC2 condom. In almost all condom uses (98.5%) the lubricant for the Origami condom was used. For the Origami condom, lubrication was used- on the penis before and during sex; in the anus before and during intercourse; and on the inside and outside of the condom before and during intercourse. More than half the males reported using another lubricant with the FC2 condom (58.5%) and only 29.2% used another lubricant with the Origami condom. Other lubricants used were "Mosaic", "Health4Man", "KY Jelly", "NACOSA" and "plain yoghurt".

**Table 5: Lubrication use for both condom types**

N	FC2 Heterosexual females N=65	Origami_ Heterosexual females N=65	FC2_ Homosexual males N=65	Origami_ Homosexual males N=65
<b>Used study lubricant n (%)</b>				
Yes	2 (3.1)	65 (100)	30 (46.2)	64 (98.5)
No	63 (96.9)	-	35 (53.9)	1 (1.5)
<b>Lubricant on penis</b>	1	37	14 (21.5)	32 (49.2)
-on penis before sex	1 (50)	30 (81.1)	11 (16.9)	25 (38.5)
-on penis during sex	-	7 (18.9)	5 (7.7)	7 (10.8)
<b>lubricant on vagina/anus</b>	-	2	18 (27.7)	35 (53.8)
-on vagina/anus before sex	-	1 (50)	15 (23.1)	34 (52.3)
-on vagina/anus during sex	-	1 (50)	3 (4.6)	1 (1.5)
<b>lubricant inside condom</b>	-	11	2 (3.1)	19 (29.2)
- inside condom before sex	-	11 (100)	1 (1.5)	18 (27.7)
- inside condom during sex	-	-	1 (1.5)	1 (1.5)
<b>lubricant outside condom</b>	1	20	1 (1.5)	26 (40)
-outside condom before sex	1 (50)	15 (75)	-	25 (38.5)
-outside condom during sex	-	5 (25)	1 (1.5)	1 (1.5)
<b>Added non-study lubricant n (%)</b>	-	-		
No	2 (3.1)	1 (1.5)	27 (41.5)	46 (70.8)
Yes			38 (58.5)	19 (29.2)

## 7.5 Penile measurements

Men were asked to measure the length and width of their penis. In the homosexual partners the insertive partners were asked only. Not all men were willing to take their measurements. Table 6 shows the individual measurements and any related failure in condom use for anal sex use.

**Table 6: Penile measurements and related failure events**

Homosexual men	LENGTH (MM)	WIDTH (MM)	Heterosexual men	LENGTH (MM)	WIDTH (MM)
201	160	130	101	144	95
202	132	113	102	Refused	-
203	160	130	103	145	105
204	150	110	104	135	125
205	155	138	105	175	140
206	Refused	-	106	130	70
207	Couple separated	-	107	170	090
208	Refused	-	108	Not done	-
209	183	135	109	150	110
210	136	105	110	150	92
211	160	100	111	Not done	-
212	145	95	112	150	100
213	102	70	113	138	122
214	170	135	114	170	90

## 7.6 Condom Safety

Adverse events were recorded for each condom type used as shown in Table 7. Participants were instructed to record the nature (e.g. discomfort, irritation, etc.) and duration of the event using the coital diary (Condom Use Log). Safety data were collected for participants and their partners. A total of 10 events were recorded in 10 condoms. No serious adverse events were reported.

**Table 7: Adverse events, by condom type**

Condom	Number of medical events reported N	Total number of condoms used N
FC2	6	65
Origami	4	65

All six medical events reported for FC2 condom were described as pain and lasted on average for 20 minutes and less. Five of the six reports were from one heterosexual female participant, who also reported having blood stains with FC2 use. No partner medical events were reported for FC2. Four medical events were reported for the Origami condom- two of which were reported for a male participant's partner. The events were described as pain and burning. Pain duration lasted one hour for one participant, and 30 minutes each for the remaining two events. Burning duration lasted five minutes. Partners of female participants experienced no adverse events for the Origami condom.

## 7.7 Acceptability

To assess how participants liked using each type of FC, the number and percentage of participants in each category of acceptability (liked very much, liked somewhat, neither liked nor disliked, disliked

somewhat, disliked very much and did not notice/no opinion) were calculated. Acceptability endpoints were calculated for all participants who completed the study with at least one condom use, thus acceptability outcomes were determined for the enrolled: 26 heterosexual women, 25 homosexual men, and 11 heterosexual men (female participant partners). Acceptability endpoints included: feel/sensation, length, amount of lubrication, appearance, ease of use, scent, colour and overall fit. Results of analyses of acceptability endpoints (features) for each condom type are shown in Table 8 and 9.

**Table 8: Acceptability of the FC2 compared to the Origami Condom**

Acceptability Features	Heterosexual women		Homosexual men		Heterosexual men
	FC2 N=13 (%)	Origami n =13(%)	FC2 N=25 (%)	Origami n =25(%)	Origami N=11 (%)
<b>Length</b>					
Liked very much	1 (7.7)	2 (15.4)	4 (16)	6 (24)	2 (18.2)
Liked somewhat	10 (76.9)	4 (30.8)	11 (44)	10 (40)	3 (27.3)
Neither liked or disliked	1 (7.7)	2 (15.4)	6 (24)	3 (12)	2 (18.2)
Disliked somewhat	1 (7.7)	5 (38.5)	3 (12)	6 (24)	2 (18.2)
Disliked very much	-	-	1 (4)	-	2 (18.2)
Did not notice/no opinion	-	-	-	-	-
<b>Amount of lubrication</b>					
Liked very much	2 (15.4)	7 (53.8)	2 (8)	10 (40)	7 (63.6)
Liked somewhat	9 (69.2)	2 (15.4)	11 (44)	7 (28)	3 (27.3)
Neither liked or disliked	1 (7.7)	1 (7.7)	6 (24)	1 (4)	-
Disliked somewhat	1 (7.7)	2 (15.4)	6 (24)	5 (20)	1 (9.1)
Disliked very much	-	-	-	1 (4)	-
Did not notice/no opinion	-	1 (7.7)	-	1 (4)	-
<b>Appearance before insertion</b>					
Liked very much	2 (15.4)	-	2 (8)	4 (16)	3 (27.3)
Liked somewhat	9 (69.2)	3 (23.1)	9 (36)	9 (36)	4 (36.4)
Neither liked or disliked	1 (7.7)	3 (23.1)	6 (24)	2 (8)	2 (18.2)
Disliked somewhat	1 (7.7)	4 (30.8)	7 (28)	7 (28)	-
Disliked very much	-	3 (23.1)	1 (4)	3 (12)	2 (18.2)
Did not notice/no opinion	-	-	-	-	-
<b>Appearance after insertion self</b>					
Liked very much	2 (15.4)	1 (7.7)	2 (8)	3 (12)	3 (27.3)
Liked somewhat	6 (46.2)	5 (38.5)	9 (36)	5 (20)	4 (36.4)
Neither liked or disliked	3 (23.1)	3 (23.1)	8 (32)	9 (36)	1 (9.1)
Disliked somewhat	1 (7.7)	2 (15.4)	5 (20)	5 (20)	2 (18.2)
Disliked very much	1 (7.7)	2 (15.4)	1 (4)	2 (8)	1 (9.1)
Did not notice/no opinion	-	-	-	1 (4)	-
<b>Appearance after insertion partner*</b>					
Liked very much	2 (15.4)	-	n/a	n/a	n/a
Liked somewhat	4 (30.8)	6 (46.2)	n/a	n/a	n/a
Neither liked or disliked	4 (30.8)	2 (15.4)	n/a	n/a	n/a
Disliked somewhat	-	3 (23.1)	n/a	n/a	n/a
Disliked very much	2 (15.4)	2 (15.4)	n/a	n/a	n/a

Did not notice/no opinion	1 (7.7)	-	n/a	n/a	n/a
<b>Scent</b>					
Liked very much	3 (23.1)	3 (23.1)	6 (24)	3 (12)	6 (54.6)
Liked somewhat	9 (69.2)	7 (53.8)	10 (40)	12 (48)	4 (36.4)
Neither liked or disliked	1 (7.7)	1 (7.7)	6 (24)	3 (12)	1 (9.1)
Disliked somewhat	-	-	1 (4)	3 (12)	-
Disliked very much	-	1 (7.7)	2 (8)	1 (4)	-
Did not notice/no opinion	-	1 (7.7)		3 (12)	-
<b>Colour</b>					
Liked very much	3 (23.1)	3 (23.1)	4 (16)	6 (24)	8 (72.7)
Liked somewhat	9 (69.2)	6 (46.2)	13 (52)	8 (32)	1 (9.1)
Neither liked or disliked	1 (7.7)	4 (30.8)	5 (20)	3 (12)	1 (9.1)
Disliked somewhat	-	-	2 (8)	5 (20)	1 (9.1)
Disliked very much	-	-	1 (4)	1 (4)	-
Did not notice/no opinion	-	-	-	2 (8)	-

\*Partner could not see so was not asked.

Women and heterosexual men reported more positive acceptability outcomes for the FC2 condom than Origami on length, scent and colour endpoints. Three of the 11 heterosexual men "liked somewhat" the length of the Origami. The Origami scent was "liked very much" by six of the 11 heterosexual men and eight of the 11 liked very much the colour of the Origami.

Appearance of the FC2 before insertion compared to Origami was favoured more by women. Appearance of the Origami before insertion was "liked somewhat" by most of the homosexual men (9/25) and heterosexual men (4/11). Appearance of the FC2 after insertion was preferred more by women and heterosexual men compared to Origami. Four of the 11 heterosexual men "liked somewhat" the appearance of the Origami after insertion and six of the 13 women reported that their partner's "liked somewhat" the appearance of the Origami after insertion.

In terms of overall fit inside vagina/anus before sex- (Table 9) the FC2 was favoured more by women and heterosexual men compared to Origami. Five of the 11 heterosexual males "liked very much" the overall fit of the Origami inside vagina before sex. These results were similar for the overall fit of the condoms inside vagina/anus during sex.

The feel/sensation before sex of the FC2 was favoured more by both women and homosexual men than the Origami condom. Six of the 11 heterosexual men "liked very much" the feel/sensation of Origami before sex. Similar results were found for the feel/sensation during sex.

Positive acceptability outcomes were reported for the amount of lubrication of the Origami as it was liked very much by majority of the women (7/13), homosexual men (10/25) and heterosexual men (7/11). Lubrication of the FC2 was also highly favoured by women (9/13) and homosexual men (11/25).

Most women "neither liked or disliked" the overall fit of the ring for both the FC2 and Origami outside the vagina before sex (6/13). Seven of the 25 homosexual men reported "liked somewhat" for both condoms and five of the 11 heterosexual men "liked very much" the overall fit of the ring for Origami outside the vagina before sex.

For the overall fit of the ring outside the vagina/anus during sex, majority of the women reported "neither liked or disliked" (7/13) for both condoms; majority of the homosexual men reported "disliked somewhat" for the Origami condom and "neither liked or disliked" for the FC2. Five of the 11 of the heterosexual men "liked very much" the overall fit of the Origami ring outside the vagina during sex.

**Table 9: Overall Acceptability of the FC2 compared to the Origami Condom**

Acceptability Features	Heterosexual women		Homosexual men		Heterosexual men
	FC2	Origami	FC2	Origami	Origami
N	13 n (%)	13 n (%)	25 n (%)	25 n (%)	11 n (%)
<b>Overall fit inside vagina/anus before sex</b>					
Liked very much	2 (15.4)	3 (23.1)	7 (28)	1 (4)	5 (45.5)
Liked somewhat	6 (46.2)	3 (23.1)	11 (44)	10 (40)	1 (9.1)
Neither liked or disliked	4 (30.8)	5 (38.5)	4 (16)	1 (4)	-
Disliked somewhat	1 (7.7)	1 (7.7)	3 (12)	9 (36)	4 (36.4)
Disliked very much	-	1 (7.7)	-	2 (8)	1 (9.1)
Did not notice/no opinion	-	-	-	2 (8)	-
<b>Overall fit inside vagina/anus during sex</b>					
Liked very much	2 (15.4)	3 (23.1)	8 (32)	1 (4)	5 (45.5)
Liked somewhat	4 (30.8)	2 (15.4)	10 (40)	9 (36)	1 (9.1)
Neither liked or disliked	6 (46.2)	6 (46.2)	5 (20)	5 (20)	-
Disliked somewhat	1 (7.7)	2 (15.4)	2 (8)	9 (36)	4 (36.4)
Disliked very much	-	-	-	1 (4)	1 (9.1)
Did not notice/no opinion	-	-	-	-	-
<b>Overall fit of ring outside vagina/anus before sex</b>					
Liked very much	1 (7.7)	-	3 (12)	4 (16)	5 (45.5)
Liked somewhat	5 (38.5)	4 (30.8)	7 (28)	7 (28)	2 (18.2)
Neither liked or disliked	6 (46.2)	6 (46.2)	7 (28)	4 (16)	-
Disliked somewhat	1 (7.7)	1 (7.7)	7 (28)	6 (24)	2 (18.2)
Disliked very much	-	2 (15.4)	1	3 (12)	2 (18.2)
Did not notice/no opinion	-	-	-	1 (4)	-
<b>Overall fit of ring outside vagina/anus during sex</b>					
Liked very much	1 (7.7)	-	4 (16)	2 (8)	5 (45.5)
Liked somewhat	5 (38.5)	2 (15.4)	5 (20)	8 (32)	2 (18.2)
Neither liked or disliked	7 (53.8)	7 (53.8)	11 (44)	2 (8)	-
Disliked somewhat	-	3 (23.1)	5 (20)	11 (44)	3 (27.3)
Disliked very much	-	1 (7.7)	-	-	1 (9.1)
Did not notice/no opinion	-	-	-	2 (8)	-
<b>Feel/sensation before sex</b>					
Liked very much	2 (15.4)	1 (7.7)	10 (40)	5 (20)	6 (54.6)
Liked somewhat	8 (61.5)	3 (23.1)	6 (24)	7 (28)	3 (27.3)
Neither liked or disliked	2 (15.4)	4 (30.8)	6 (24)	5 (20)	-
Disliked somewhat	1 (7.7)	2 (15.4)	3 (12)	7 (28)	-
Disliked very much	-	2 (15.4)	-	-	2 (18.2)
Did not notice/no opinion	-	1 (7.7)	-	1 (4)	-
<b>Feel/sensation during sex</b>					
Liked very much	2 (15.4)	2 (15.4)	4 (16)	8 (32)	6 (54.6)
Liked somewhat	8 (61.5)	2 (15.4)	13 (52)	6 (24)	2 (18.2)
Neither liked or disliked	2 (15.4)	4 (30.8)	7 (28)	4 (16)	1 (9.1)
Disliked somewhat	1 (7.7)	4 (30.8)	1 (4)	5 (20)	-
Disliked very much	-	-	-	1 (4)	2 (18.2)
Did not notice/no opinion	-	1 (7.7)	-	1 (4)	-



## 7.8 Condom Preference

Eight of the 11 male heterosexual participants liked the Origami condom the best overall (72.7%); two of the 11 liked the FC2 condom (18.2%) and one did not like either condom (9.1%). The majority (11/13) of the female heterosexual participants liked the FC2 condom best (84.6%). One liked the Origami condom best and another liked both condom types the same (7.7%). Of the 25 homosexual male participants, just over half (14/25) (56%) liked the FC2 best compared to (9/25) 36% who liked the Origami condom best. Two liked both condom types the same (8%).

## 8. Conclusion

Functionality was found to be similar between FC2 and Origami in the homosexual couples. Failure rates were lower in FC2 for heterosexual couples while the Origami rates of failure remained high. Generally the failure rates in homosexual couple was higher than seen in vaginal sex for FC2 in this study and in other published female condom functionality studies and this may be related to the use of the condoms for anal sex. The ring was removed for FC2 in homosexual couples which is always recommended as it may cause pain in the anus. However this may make the condom less stable.

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## 10. APPENDICES

### 10.1 Female Baseline Survey CCC

#### BASELINE SURVEY

#### A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

1. Study Number:   O  |  I  |  C  |  1  |
2. Participant Number:       |      |      |      |-      |      |
3. Date of Interview:       |      | /       |      | /       |      |      |      | (dd/mm/yyyy)
4. Interviewer Number:       |      |      |

DEMOGRAPHIC INFORMATION (ULWAZI OLUPHATHELENE NAWU)	
5. How old are you in years? ( <i>Ingabe uneminyaka emingaki?</i> )	<u>              </u>
6. With which group do you most identify? ( <i>Yiluphi uhlanga lwakho?</i> ) 1 = Black ( <i>Omnyama</i> ) 2 = Coloured ( <i>Ikhalaadi</i> ) 3 = White ( <i>Omhlomphe</i> ) 4 = Indian ( <i>Indiya</i> ) 5 = Asian ( <i>Ishayina</i> ) 6 = Asian Other, specify ( <i>chaza</i> ): _____	<u>              </u>
7. How many years of school (grades) have you completed? ( <i>Ufunde iminyaka emingaki esikoleni?</i> ) <b>For Numbers 0-9, please write "00, 01, etc."</b>	<u>              </u>
8. What is your <u>primary</u> occupation? ( <i>Wenza msebenzi muni?</i> ) 00 = None/Unemployed ( <i>Angisebenzi</i> ) 01 = Self Employed ( <i>Ngiyazisebenza</i> ) 02 = Unskilled Labour ( <i>Ngenza umsebenzi ongafundelwa</i> ) 03 = Health/Medical ( <i>Umkhakha wezempilo</i> ) 04 = Office ( <i>Ehovisi</i> ) 05 = Public Service/Government ( <i>Isisebenzi sikahulumeni</i> ) 06 = Sales ( <i>Ngiyadayisa</i> ) 07 = Student ( <i>Ngiyafunda</i> ) 08 = Teacher/Lecturer ( <i>Ngiyafundisa</i> ) 09 = Technical ( <i>Umsebenzi wobuchwepheshe</i> ) 10 = Other, specify ( <i>Okunye, chaza</i> ) _____	<u>              </u>
9. How many <u>living</u> children do you have? ( <i>Zingaki izingane zakho eziphilayo?</i> ) <b>For Numbers 0-9, please write "00, 01, etc."</b>	<u>              </u>
10. How would you describe your relationship with your current spouse/partner? ( <i>Ungabuchaza kanjani.ubudlelwano bakho nohlekisana naye njengamanje?</i> ) 1 = Married and living together ( <i>Ushadile nihlala ndawonye</i> ) 2 = Married and not living together ( <i>Ushadile anihlali ndawonye</i> ) 3 = Not married and living together ( <i>Anishadile kodwa nihlala ndawonye</i> ) 4 = Not married and not living together ( <i>Anishadile anihlali ndawonye</i> ) 5 = Other, specify ( <i>Okunye, chaza</i> ): _____	<u>              </u>
11. How long have you had a relationship with your spouse/partner? ( <i>Ninesikhathi esingakanani nithandana nomlingani wakho/ohlekisana naye?</i> ) 1 = Less than 1 year ( <i>Ngaphansi konyaka</i> ) 2 = 1-5 years ( <i>Owodwa kuya kwemihlanu</i> ) 3 = 6-10 years ( <i>Ewu 6 kuya ku 10</i> ) 4 = More than 10 years ( <i>Ngaphezu kuka 10</i> )	<u>              </u>

<b>HISTORY OF MALE CONDOM USE (UMLANDO WOKUSEBENZISA IKHONDOMU YABESILISA)</b>	
<b>12.</b> Did you use a <u>male</u> condom the <u>last</u> time you and your spouse/partner had vaginal sex? ( <i>Ngenkathi nigcina ukuya ocansini nayisebenzisa ikhondomu yabesilisa?</i> ) NO (CHA) = 0 → go to Question 14. YES (YEBO) = 1 → go to Question 13.	_ _
<b>13.</b> About how often have you used <u>male</u> condoms with your spouse/partner in the past 6 months? ( <i>Kukangaki nisebensisa ikhondomu yabesilisa kulezinyanga eziyisithupha ezedlule?</i> ) <b>READ ALL OPTIONS</b> 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> ) 2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	_ _
<b>HISTORY OF FEMALE CONDOM USE (UMLANDO WOKUSEBENZISA IKHONDOMU YABESIFAZANE)</b>	
<b>14.</b> Have you ever used a <u>female</u> condom? ( <i>Wake wayisebenzisa ikhondomu yabesifazane?</i> ) NO (CHA) = 0 → go to Question 17. YES (YEBO) = 1 → go to Question 15.	_ _
<b>15.</b> Did you use a <u>female</u> condom the <u>last</u> time you and your spouse/partner had vaginal sex? ( <i>Niyisebenzisile yini ikhondomu yabesifazane ngesikhathi nigcina ukuya ocansini wena nomlingani wakho/ohlekisana naye?</i> ) NO (CHA) = 0 YES (YEBO) = 1	_ _
<b>16.</b> About how often have you used <u>female</u> condoms with your spouse/partner in the past 6 months? ( <i>Kukangaki nisebenzisa amakhondomu abesifazane nomlingani wakho/ohlekisana naye, ezinyangeni eziyisithupha ezedlule?</i> ) <b>READ ALL OPTIONS</b> 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> ) 2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	_ _
<b>USE OF OTHER PRODUCTS Zulu</b>	
<b>17.</b> Have you ever used tampons? ( <i>Uke wasebenzisa ithemponi?</i> ) NO (CHA) = 0 YES (YEBO) = 1	_ _
<b>18.</b> Have you ever douched or placed medicine inside your vagina? ( <i>Uke wageza noma washutheka imithi esithweni sakho sangasese</i> ) NO (CHA) = 0 YES (YEBO) = 1	_ _
<b>19.</b> Have you ever used personal or sexual lubricant? (translate to Zulu) NO (CHA) = 0 → go to end of Q. YES (YEBO) = 1 → go to Question 20.	_ _
<b>20.</b> In the past 6 months how often have you used personal or sexual lubricants when you have sex? 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> ) 2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	_ _

## 10.2 Male Baseline Survey DLGCHC

### BASELINE SURVEY

#### A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

1. Study Number:   O  I  C  1
2. Participant Number:       -
3. Date of Interview:        /        /        (dd/mm/yyyy)
4. Interviewer Number:

DEMOGRAPHIC INFORMATION (ULWAZI OLUPHATHELENE NAWU)	
21. How old are you in years? ( <i>Ingabe uneminyaka emingaki?</i> )	<u>      </u>
22. With which group do you most identify? ( <i>Yiluphi uhlanga lwakho?</i> ) 1 = Black ( <i>Omnyama</i> ) 2 = Coloured ( <i>Ikhala</i> ) 3 = White ( <i>Omhlophe</i> ) 4 = Indian ( <i>Indiya</i> ) 5 = Asian ( <i>Ishayina</i> ) 6 = Asian Other, specify ( <i>chaza</i> ): _____	<u>      </u>
23. How many years of school (grades) have you completed? ( <i>Ufunde iminyaka emingaki esikoleni?</i> ) <b>For Numbers 0-9, please write "00, 01, etc."</b>	<u>      </u>
24. What is your <u>primary</u> occupation? ( <i>Wenza msebenzi muni?</i> ) 00 = None/Unemployed ( <i>Angisebenzi</i> ) 01 = Self Employed ( <i>Ngizisebenza</i> ) 02 = Unskilled Labour ( <i>Ngenza umsebenzi ongafundelwa</i> ) 03 = Health/Medical ( <i>Umkhakha wezempilo</i> ) 04 = Office ( <i>Ehovisi</i> ) 05 = Public Service/Government ( <i>Isisebenzi sikahulumeni</i> ) 06 = Sales ( <i>Ngiyadayisa</i> ) 07 = Student ( <i>Ngiyafunda</i> ) 08 = Teacher/Lecturer ( <i>Ngiyafundisa</i> ) 09 = Technical ( <i>Umsebenzi wobuchwepheshe</i> ) 10 = Other, specify ( <i>Okunye, chaza</i> ) _____	<u>      </u>
25. How would you describe your relationship with your current spouse/partner? ( <i>Ungabuchaza kanjani.ubudlelwano bakho nohlelisana naye njengamanje?</i> ) 1 = Married and living together ( <i>Ushadile nihlala ndawonye</i> ) 2 = Married and not living together ( <i>Ushadile anihlali ndawonye</i> ) 3 = Not married and living together ( <i>Anishadile kodwa nihlala ndawonye</i> ) 4 = Not married and not living together ( <i>Anishadile anihlali ndawonye</i> ) 5 = Other, specify ( <i>Okunye, chaza</i> ): _____	<u>      </u>
26. How long have you had a relationship with your spouse/partner? ( <i>Ninesikhathi esingakanani nithandana nomlingani wakho/ohlelisana naye?</i> ) 1 = Less than 1 year ( <i>Ngaphansi konyaka</i> ) 2 = 1-5 years ( <i>Owodwa kuya kwemihlanu</i> ) 3 = 6-10 years ( <i>Ewu 6 kuya ku 10</i> ) 4 = More than 10 years ( <i>Ngaphezu kuka 10</i> )	<u>      </u>
HISTORY OF MALE CONDOM USE (UMLANDO WOKUSEBENZISA IKHONDOMU YABESILISA)	
27. Did you use a <u>male</u> condom the <u>last</u> time you and your spouse/partner had anal sex? ( <i>Ngenkathi nigcina ukuya ocansini nayisebenzisa ikhondomu yabesilisa?</i> ) NO ( <i>CHA</i> ) = 0 → go to Question 13. YES ( <i>YEBO</i> ) = 1 → go to Question 12.	<u>      </u>
28. About how often have you used <u>male</u> condoms with your partne/spouse in the past 6 months? ( <i>Kukangaki nisebensisa ikhondomu yabesilisa kulezinyanga eziyisithupha ezedlule?</i> ) <b>READ ALL OPTIONS</b> 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> )	<u>      </u>

2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	
<b>HISTORY OF FEMALE CONDOM USE (UMLANDO WOKUSEBENZISA IKHONDOMU YABESIFAZANE)</b>	
<b>29.</b> Have you ever used a <u>female</u> condom? ( <i>Wake wayisebenzisa ikhondomu yabesifazane?</i> ) NO ( <i>CHA</i> ) = 0 ➔ go to Question 16. YES ( <i>YEBO</i> ) = 1 ➔ go to Question 14.	<input type="text"/>
<b>30.</b> Did you use a <u>female</u> condom the <u>last</u> time you and your spouse/partner had anal sex? ( <i>Niyisebenzisile yini ikhondomu yabesifazane ngesikhathi nigcina ukuya ocansini wena nomlingani wakho/ohlekisana naye?</i> ) NO ( <i>CHA</i> ) = 0 YES ( <i>YEBO</i> ) = 1	<input type="text"/>
<b>31.</b> About how often have you used <u>female</u> condoms with your spouse/partner in the past 6 months? ( <i>Kukangaki nisebenzisa amakhondomu abesifazane nomlingani wakho/ohlekisana naye, ezinyangeni eziyisithupha ezedlule?</i> ) <b>READ ALL OPTIONS</b> 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> ) 2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	<input type="text"/>
<b>HISTORY OF PRODUCT USE (translate to Zulu)</b>	
<b>32.</b> Have you ever douched inside your anus? ( <i>Uke wageza noma washutheka imithi esithweni sakho sangasese</i> ) NO ( <i>CHA</i> ) = 0 YES ( <i>YEBO</i> ) = 1	<input type="text"/>
<b>33.</b> Have you ever used personal or sexual lubricant? (translate to Zulu) NO ( <i>CHA</i> ) = 0 ➔ go to end of Q. YES ( <i>YEBO</i> ) = 1 ➔ go to Question 18.	<input type="text"/>
<b>34.</b> In the past 6 months how often have you used personal or sexual lubricants when you have sex? (translate to Zulu) 0 = Never ( <i>Nhlobo</i> ) 1 = Less than half the time ( <i>Ngaphansi kohafu wesikhathi</i> ) 2 = Half the time ( <i>Uhafu wesikhathi</i> ) 3 = More than half the time ( <i>Ngaphezu kohafu wesikhathi</i> ) 4 = Every time ( <i>Njalo</i> )	<input type="text"/>

## 10.3 Condom Use Log Female CCC

### OPENING AND DONNING THE

1. **How did you open the condom package?**  
(Check one)  
☐ 1= With fingers  
☐ 2= With teeth  
☐ 3= With sharp object  
☐ 4= Other, *Describe:* \_\_\_\_\_
2. **Did the condom break or tear while opening the package?**  
☐ 0= No  
☐ 1= Yes: *Answer Question 17 only.*
3. **Did the condom appear to be in good condition?**  
☐ 1= Yes  
☐ 0= No,  
*Explain:* \_\_\_\_\_
4. **Was the condom inserted?**  
☐ 1= Yes  
☐ 0= No, *Please explain*  
\_\_\_\_\_  
\_\_\_\_\_
5. **When was the condom inserted?**  
☐ 1= Before intercourse started: \_\_\_\_\_ minutes before  
☐ 2= After intercourse started: \_\_\_\_\_ minutes after
6. **Did you have vaginal intercourse using this**

### INTERCOURSE INFORMATION

condom?

- ☐ 1= Yes  
☐ 0= No, *please explain:* \_\_\_\_\_
7. **Did you use the study lubricant during this condom use? (Check all that apply)**  
☐ 0= Not used  
☐ 1= On the penis: ☐ 1a= Before intercourse and/or  
☐ 1b= During intercourse  
☐ 2= In the vagina: ☐ 2a= Before intercourse and/or  
☐ 2b= During intercourse  
☐ 3= On the inside of the condom:  
☐ 3a= Before intercourse and/or  
☐ 3b= During intercourse  
☐ 4= On the outside of the condom:  
☐ 4a= Before intercourse and/or  
☐ 4b= During intercourse
  8. **Did you add any other, non-study lubricant?**  
☐ 1= No  
☐ 2= Yes, Specify brand: \_\_\_\_\_

### 9. Did the penis ever go between the condom and the vagina? (Check all that apply)

- ☐ 1= No: *Skip to Question 10.*  
☐ 2= At insertion of the penis:  
☐ 2a= 1 time or  
☐ 2b= more than once  
☐ 3= During intercourse:  
☐ 3a= 1 time or  
☐ 3b= more than once  
☐ 4= Don't know

### 9a. What did you do when you noticed this problem? (Check all that apply)

- ☐ 1= Stopped intercourse, reinserted the penis into the condom, and continued  
☐ 2= Continued intercourse without any attempt to adjust condom  
☐ 3= Removed the condom and continued intercourse without it  
☐ 4= Removed the condom and stopped intercourse  
☐ 5= Other, *Explain:* \_\_\_\_\_

### 10. Did the outer ring of the condom ever get pushed into the vagina?

- ☐ 1= No: *Skip to Question 11.*  
☐ 2= Yes: 1 time  
☐ 3= Yes: More than 1 time  
☐ 4= Don't know

### 10a. What did you do when you noticed this problem? (Check all that apply)

- ☐ 1= Stopped intercourse, adjusted the condom, and continued  
☐ 2= Continued intercourse no attempt to adjust condom  
☐ 3= Removed the condom and continued intercourse without it  
☐ 4= Removed the condom and stopped intercourse  
☐ 5= Other, *Explain:* \_\_\_\_\_

### 11. During intercourse, did the condom ever completely SLIP OUT of the vagina?

- ☐ 1= No: *Skip to Question 12.*  
☐ 2= Yes, clung to penis:  
☐ 2a= 1 time or  
☐ 2b= more than once  
☐ 3= Yes, did not cling to penis:  
☐ 3a= 1 time or  
☐ 3b= more than once  
☐ 4= Don't know

### 11a. What did you do when you noticed this problem? (Check all that apply)

- ☐ 1= Stopped intercourse, reinserted the condom into the vagina, and continued  
☐ 2= Removed the condom and continued intercourse without it  
☐ 3= Removed the condom and stopped intercourse  
☐ 4= Other,  
*Explain:* \_\_\_\_\_

## REMOVING AND DISPOSING OF THE

**15. During withdrawal of the penis after intercourse, did the condom completely SLIP OUT of the vagina?**

- ☐ 1= No: *Skip to Question 14*
- ☐ 2= Yes, clung to penis
- ☐ 3= Yes, did not cling to penis
- ☐ 4= Don't know

**14. During removal, was there any spillage of semen?**

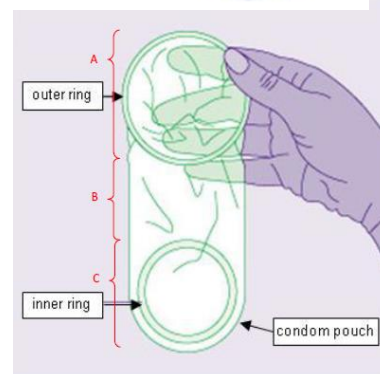
- ☐ 1= No
- ☐ 2= Yes, onto woman's genital area
- ☐ 3= Yes, away from woman's genital area

**16. When did you remove the condom?**

- ☐ 1= Before intercourse ended: \_\_\_\_\_ minutes before
- ☐ 2= After intercourse ended: \_\_\_\_\_ minutes after
- ☐ 3= Don't know/Not sure

**17. Did the condom ever break?**

- ☐ 1= No
- ☐ 2= Yes, while opening package
- ☐ 3= Yes, after opening package but before inserting it
- ☐ 4= Yes, while trying to insert it
- ☐ 6= Yes, during intercourse
- ☐ 7= Yes, during withdrawal of penis from vagina
- ☐ 8= Yes, during removal of condom from vagina
- ☐ 9= Don't know when
- ☐ 10= Other, *Describe:* \_\_\_\_\_



**17a. Where did the condom break? (Check the answer that best applies and mark on diagram with a X)**

- ☐ 1= Near outer ring
- ☐ 2= In the middle
- ☐ 3= At the tip
- ☐ 4= In more than one place

Can you explain how you think the breakage happened? \_\_\_\_\_

**18. Did you have a medical problem while using this condom? Specify duration (time) that the medical problem lasted (If yes, complete AE form)**

- ☐ 1= No
- ☐ 2= Yes, Itching → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 3= Yes, burning → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 4= Yes, pain → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 5= Yes, rash → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 6= Yes, other, specify \_\_\_\_\_ → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)

**19. Did your partner have a medical problem while using this condom? Specify duration (time) that the medical problem lasted. (if yes, complete AE form)**

- ☐ 1= No
- ☐ 2= Yes, Itching → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 3= Yes, burning → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 4= Yes, pain → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 5= Yes, rash → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)
- ☐ 6= Yes, other, specify \_\_\_\_\_ → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)



## 10.4 Condom Use Log Male DLGCHC

### OPENING AND DONNING THE

**1. How did you open the condom package?  
(Check one)**

- ☐ 1= With fingers  
☐ 2= With teeth  
☐ 3= With sharp object  
☐ 4= Other, *Describe:* \_\_\_\_\_

**2. Did the condom break or tear while opening the package?**

- ☐ 0= No  
☐ 1= Yes *skip to Q 16*  
☐ 2= Not sure

**3. Did the condom appear to be in good condition?**

- ☐ 1= Yes  
☐ 0= No, *Explain:* \_\_\_\_\_

**4. Was the condom inserted?**

- ☐ 1= Yes  
☐ 0= No, *Please explain*  
\_\_\_\_\_

**5. When was the condom inserted?**

- ☐ 1= Before intercourse started: \_\_\_\_\_ minutes before  
☐ 2= After intercourse started: \_\_\_\_\_ minutes after

**6. Did you remove the inner ring before intercourse**

- ☐ 1= Yes, inner ring removed  
☐ 0= No, inner ring left inside condom  
☐ 2= N/A no ring inside this condom

### INTERCOURSE INFORMATION

**7. Did you have anal intercourse using this condom?**

- ☐ 1= Yes  
☐ 0= No, *please explain:* \_\_\_\_\_ Go to 16

**8. Did you use the study lubricant during this condom use?  
(Check all that apply)**

- ☐ 0= Not used  
☐ 1= On the penis: ☐ 1a= Before intercourse and/or  
☐ 1b= During intercourse  
☐ 2= In the anus: ☐ 2a= Before intercourse and/or  
☐ 2b= During intercourse  
☐ 3= On the inside of the condom:  
☐ 3a= Before intercourse and/or  
☐ 3b= During intercourse  
☐ 4= On the outside of the condom:  
☐ 4a= Before intercourse and/or  
☐ 4b= During intercourse

**9. Did you add any other, non-study lubricant?**

- ☐ 1= No  
☐ 2= Yes, Specify brand name: \_\_\_\_\_

**10. Did the penis ever go between the condom and the anus?  
(Check all that apply)**

- ☐ 1= No: *Skip to Question 11.*  
☐ 2= At insertion of the penis:  
☐ 2a= 1 time or  
☐ 2b= more than once  
☐ 3= During intercourse:  
☐ 3a= 1 time or  
☐ 3b= more than once  
☐ 4= Don't know

**10a. What did you do when you noticed this problem? (Check all that apply)**

- ☐ 1= Stopped intercourse, reinserted the penis into the condom, and continued  
☐ 2= Continued intercourse without any attempt to adjust condom  
☐ 3= Removed the condom and continued intercourse without it  
☐ 4= Removed the condom and stopped intercourse  
☐ 5= Other, *Explain:* \_\_\_\_\_

**11. Did the outer ring of the condom ever get pushed into the anus?**

- ☐ 1= No: *Skip to Question 12.*  
☐ 2= Yes: 1 time  
☐ 3= Yes: More than 1 time  
☐ 4= Don't know

**11a. What did you do when you noticed this problem? (Check all that apply)**

- ☐ 1= Stopped intercourse, adjusted the condom, and continued  
☐ 2= Continued intercourse no attempt to adjust condom  
☐ 3= Removed the condom and continued intercourse without it  
☐ 4= Removed the condom and stopped intercourse  
☐ 5= Other, *Explain:* \_\_\_\_\_

**12. During intercourse, did the condom ever completely SLIP OUT of the anus?**

- ☐ 1= No: *Skip to Question 13.*  
☐ 2= Yes, clung to penis:  
☐ 2a= 1 time or  
☐ 2b= more than once  
☐ 3= Yes, did not cling to penis:  
☐ 3a= 1 time or  
☐ 3b= more than once  
☐ 4= Don't know

**12a. What did you do when you noticed this problem? (Check all that apply)**

- ☐ 1= Stopped intercourse, reinserted the condom into the anus, and continued  
☐ 2= Removed the condom and continued intercourse without it  
☐ 3= Removed the condom and stopped intercourse  
☐ 4= Other,  
*Explain:* \_\_\_\_\_

## REMOVING AND DISPOSING OF THE

condom completely SLIP OUT of the anus?

- ☐ 1= No: *Skip to Question 14*  
☐ 2= Yes, clung to penis  
☐ 3= Yes, did not cling to penis  
☐ 4= Don't know

14. During removal, was there any spillage of semen?

- ☐ 1= No  
☐ 2= Yes, onto the anal area  
☐ 3= Yes, away from the anal area

15. When did you remove the condom?

- ☐ 1= Before intercourse ended: \_\_\_\_\_ minutes before  
☐ 2= After intercourse ended: \_\_\_\_\_ minutes after  
☐ 3= Don't know/Not sure

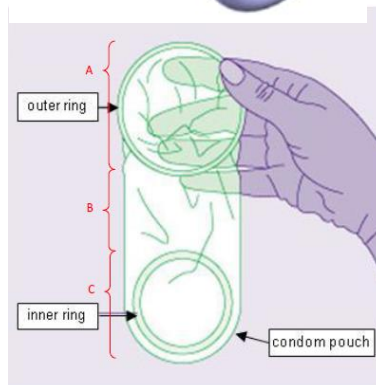
16. Did the condom ever break?

- ☐ 1= No  
☐ 2= Yes, while opening package  
☐ 3= Yes, after opening package but before inserting it  
☐ 4= Yes, while trying to insert it  
☐ 5= Yes, after inserting it but before intercourse began  
☐ 6= Yes, during intercourse  
☐ 7= Yes, during withdrawal of penis from anus  
☐ 8= Yes, during removal of condom from anus  
☐ 9= Don't know when  
☐ 10= Other, *Describe:* \_\_\_\_\_

16a. Where did the condom break? (Check the answer that best applies and mark on diagram with cross)

- ☐ 1= Near outer ring  
☐ 2= In the middle  
☐ 3= At the tip  
☐ 4= In more than one place

Can you explain how you think the breakage happened?



17. Did you have a medical problem while using this condom? Specify duration (time) that the medical problem lasted (if yes complete an AE form)

- ☐ 1= No  
☐ 2= Yes, Itching → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 3= Yes, burning → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 4= Yes, pain → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 5= Yes, rash → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 6= Yes, other, specify \_\_\_\_\_ → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)

18. Did your partner have a medical problem while using this condom? Specify duration (time) that the medical problem lasted. (if Yes complete an AE form)

- ☐ 1= No  
☐ 2= Yes, Itching → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 3= Yes, burning → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 4= Yes, pain → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 5= Yes, rash → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)  
☐ 6= Yes, other, specify \_\_\_\_\_ → Duration: \_\_\_\_ : \_\_\_\_ (hours: minutes)

## 10.5 Follow-up Survey 1 Female CCC

### FOLLOW-UP VISIT 1 SURVEY A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

4. Study Number:   O  I  C  1
5. Participant Number:       -
6. Date of Interview:       /      /       (dd/mm/yyyy)
4. Interviewer Number:
5. Follow-up Visit Number:
6. Participant Randomization Sequence:

<p><b>7. Were the written instructions for how to use this study condom easy to follow?</b> (Ingabe kwakulula ukulandela imiyalelo eyayibhaliwe yokuthi ungayisebenzisa kanjani lekhondomu yabesifazane?)</p> <p>1 = NO (CHA) 2 = YES (YEBO) If NO, why? (Uma uthi cha kungani?) _____</p>	<u>      </u>
<p><b>8. Did you insert each study study condom into your vagina the same way every time you used the study condoms?</b> (Ubuwafaka ngendlela efanayo njalo yini lamakhondomu abesifazane ocwaningo enkomeni uma uwasebenzisa?)</p> <p>1 = NO (CHA) 2 = YES (YEBO)</p>	<u>      </u>
<p><b>9. How did you insert these study study condoms?</b> (Uwafake kanjani lamakhondomu abesifazane ocwaningo?)</p> <p>Mark <u>X</u> all that apply. (Makha ngo X konke okungenayo.)</p> <p><u>      </u> a. I placed the study condoms in my vagina as instructed. (Amakhondomu abesifazane ngawafaka ngendlela engatshelwe ngayo enkomeni yami.)</p> <p><u>      </u> b. My spouse/partner placed the study condoms in my vagina. (Umkhwenyana/uphathina wami wawafaka amakhondomu abesifazane enkomeni yami.)</p> <p><u>      </u> c. The study condom was inserted into my vagina on my partners penis. ( Zulu)</p> <p><u>      </u> d. Other, explain (Okunye, uchaze): _____</p>	
<p><b>10. How easy was it to insert these study study condoms?</b> (Kwakulula kangakanani ukufaka lamakhondomu abesifazane ocwaningo?) <b>READ ALL OPTIONS</b></p> <p>1 = Very difficult (Kubukhuni kakhulu) 2 = Difficult, but improved with practice (Kubukhuni kodwa kuba ngcono ngokujwayela) 3 = Easy (Kulula) 4 = Very easy (Kulula kakhulu)</p>	<u>      </u>
<p><b>11. At any time during sex did any of the study condoms slip some or all of the way out of the vagina or move in and out on the partner's penis?</b> (check condom log for</p>	

<p><i>slippage Q X for any of the condoms used, this Q is additionally probing for any slippage during sex) (Zulu)</i></p> <p>1=NO (CHA) → go to Question 13.          2=YES (YEBO) → go to Question 12.          3= Unsure (zulu) → go to Question 13.</p>	<div style="border: 1px solid black; height: 20px; width: 50px;"></div>																														
<p><b>12. For each condom which slipped some or all of the out of the vagina or moved in and out on the partners penis please can you give us more detail about what happened? (Zulu, all)</b></p> <p><b>Mark [X] for all that apply and explain below table.</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Condom use number</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> </thead> <tbody> <tr> <td>The condom slipped partially but not completely out of my vagina during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom slipped out of my vagina completely during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom seemed to be moving in and out on my partners penis during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom slipped out on my partner's penis after he withdrew after sex.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p><b>Use this space below to describe the event in more detail if required, noting which condom use the event is referring too.</b></p> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border-bottom: 1px solid black; height: 40px; margin-bottom: 10px;"></div>		Condom use number	1	2	3	4	5	The condom slipped partially but not completely out of my vagina during sex						The condom slipped out of my vagina completely during sex						The condom seemed to be moving in and out on my partners penis during sex						The condom slipped out on my partner's penis after he withdrew after sex.					
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<p><b>13. For each study condom used can you describe the position of the outer ring <u>before you removed it from the vagina after sex</u>, compared to the position it was in when you inserted it?</b>  <i>( Check condom log and ask the woman to show the position on the pelvic model if unsure how to describe the position, check again if the event happened during or after sex) (Zulu, all)</i></p> <p><b>Mark [X] all that apply.</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Condom use</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> </thead> <tbody> <tr> <td>Outer ring <u>outside</u> the vagina, in the same place as when inserted and before sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Outer ring <u>outside</u> the vagina but some of the condom had moved out further from vagina.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Condom use	1	2	3	4	5	Outer ring <u>outside</u> the vagina, in the same place as when inserted and before sex						Outer ring <u>outside</u> the vagina but some of the condom had moved out further from vagina.																	
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Outer ring <u>outside</u> the vagina but some of the condom had moved further into the vagina.							
All or part of outer ring <u>inside</u> the vagina (should be marked on condom log)							
Not sure as my partner/spouse removed the study condom from my vagina							
The condom slipped out on my partner's penis after he withdrew after sex.							
Not sure/Cannot remember							

**14. Did you remove each of the study study condoms from your vagina in the same way?** (*Wawakhipha ngendlela efanayo yini amakhondomu ebesifazane enkomeni yakho?*)

1 = NO (*CHA*)  
2 = YES (*YEBO*)

**15. How did you remove the study study condoms from your vagina?** (*Uwakhiphe kanjani enkomeni yakho lamakhondomu abesifazane ocwaningo?*)  
**Mark ☒ all that apply.** (*Makha ngo X konke okungenayo.*)

☐ a. My spouse/partner removed the study condom from my vagina. (*Umkhwenyana/Uphathina wayifaka ikhondomu yabesifazane enkomeni yami.*)

☐ b. I twisted the open end (outer frame) and pulled the study condom out of my vagina as instructed. (*Ngasonta iringi yangaphandle yekhondomu yabesifazane futhi ngayidonsela ngaphandle enkomeni yami ngokucophelela njengoba ngatshelwa.*)

☐ c. I pulled the study condoms straight out of my vagina without twisting the condoms. (*Ngavele nje ngawadonsela ngaphandle enkomeni yami amakhondomu abesifazane ngaphandle kokuwasonta amakhondomu.*)

☐ d. The study condom pulled out on my spouse/partner's penis when he withdrew his penis from my vagina. (*Ikhondomu yabesifazane yaziphumela yona epipini lika mkhwenyana/phathina wami ngenkathi ekhipha Ipipi lakhe enkomeni yami.*)

☐ e. Other, explain (*Okunye, uchaze*): \_\_\_\_\_

**16. Please rate each feature of this study condom as follows:** (*Ngicela ungikalele isakhiwo salekhondomu yabesifazane ngasodwana njengokulandelayo: Write one number response in every box. (Bhala Inombolo eyodwa eyimpendulo kuwowonke amabhokiso.) READ ALL OPTIONS*)

1 = Liked very much (*Ngiyithandile kakhulu*)  
2 = Liked somewhat (*Ngiyithandile ngandlelathize*)  
3 = Neither liked or disliked (*Phakathi kokuyithanda nokungayithandi*)  
4 = Disliked somewhat (*Angiyithandi ndlelathize*)  
5 = Disliked very much (*Angiyithandi kakhulu*)  
6= Did not notice/no opinion/did not see

	<i>Feature</i>	<i>Before sex/observation</i>	<i>During sex</i>
a.	<i>Length (Ubude)</i>		

b.	Amount of lubrication ( <i>Ubungako bamafutha okugcoba</i> )		
c.	Appearance before insertion ( <i>Ukubukeka</i> )		
d.	Appearance after insertion (external feature on body) ( <i>zulu</i> )	Self  ____  partner ____	
e.	Scent ( <i>Iphunga</i> )		
f.	Colour ( <i>Umbala</i> )		
g.	Overall fit inside vagina ( <i>Ukulingana kwayo konke</i> )		
h.	Overall fit of ring outside vagina ( <i>zulu</i> )		
i.	Feel/sensation ( <i>Ukuzwakala</i> )		

<p><b>17. How did you like using this study condom?</b> (<i>Wakuthanda kanjani ukusebenzisa lekhondomu yabesifazane?</i>) <b>READ ALL OPTIONS</b></p> <p>1 = Liked very much (<i>Ngiyithandile kakhulu</i>) → <b>Go to Q. 18</b>  2 = Liked somewhat (<i>Ngiyithandile ngandlelathize</i>) → <b>Go to Q. 18</b>  3 = Neither liked nor disliked (<i>Phakathi kokuyithanda nokungayithandi</i>)  4 = Disliked somewhat (<i>Angiyithandi ndlelathize</i>) → <b>Go to Q. 19</b>  5 = Disliked very much (<i>Angiyithandi kakhulu</i>) → <b>Go to Q. 19</b></p>	____
<p><b>18. Why did you <u>like</u> using this study condom?</b> (<i>Kungani wathanda ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>19. Why did you <u>dislike</u> using this study condom?</b> (<i>Kungani ungathandanga ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>20. During sex did you feel the condom was stable (stayed in one place) (zulu)</b>  1 = NO (any of 5 uses) (<i>CHA</i>)  2 = YES, in every use (<i>YEBO</i>)  If NO, why _____</p>	____
<p><b>21. Was this study condom comfortable to use?</b> (<i>Ingabe kwakulula ukusebenzisa lekhondomu yabesifazane?</i>)</p> <p>1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If NO, why _____</p>	____
<p><b>22. If you had a choice of using this study condom and a male condom which would you prefer?</b></p> <p>1 = Study condom</p>	____

<p>2= Male condom</p> <p>Please can you briefly explain your choice_____</p> <p>_____</p>	
<p><b>23. Would you recommend this study condom to a friend? (zulu)</b></p> <p>1 = NO (CHA) 2 = YES (YEBO)</p> <p>If <b>NO</b>, why(Uma uthi cha, kungani?)</p> <p>_____</p>	<p> ____ </p>
<p><b>24. Would you be interested in using this study condom in future? (zulu)</b></p> <p>1 = NO (CHA) 2 = YES (YEBO)</p> <p>If <b>NO</b>, why(Uma uthi cha, kungani?)</p> <p>_____</p>	<p> ____ </p>

## 10.6 Follow-up Survey 1 Males DLGCHC

### FOLLOW-UP VISIT 1 SURVEY A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

7. Study Number:   O  I  C  1
8. Participant Number:       -
9. Date of Interview:        /        /        (dd/mm/yyyy)
10. Interviewer Number:
11. Follow-up Visit Number:
6. Participant Randomization Sequence:

<p><b>7. Were the written instructions for how to use this study condom easy to follow?</b> (<i>Ingabe kwakulula ukulandela imiyalelo eyayibhaliwe yokuthi ungayisebenzisa kanjani lekhondomu yabesifazane?</i>)</p> <p>1 = NO (CHA) 2 = YES (YEBO)</p> <p>If NO, why? (<i>Uma uthi cha kungani?</i>) _____</p>	<input style="width: 50px;" type="text"/>
<p><b>8. Did you insert each study condom into your anus the same way every time you used the female condoms?</b> (<i>Ubuwafaka ngendlela efanayo njalo yini lamakhondomu abesifazane ocwaningo enkomeni uma uwasebenzisa?</i>)</p> <p>1 = NO (CHA) 2 = YES (YEBO)</p>	<input style="width: 50px;" type="text"/>
<p><b>9. How did you insert these study condoms?</b> (<i>Uwafake kanjani lamakhondomu abesifazane ocwaningo?</i>)</p> <p><b>Mark <input checked="" type="checkbox"/> all that apply.</b> (<i>Makha ngo X konke okungenayo.</i>)</p> <p><input type="checkbox"/> a. I placed the condoms in my anus as instructed with ring removed. (<i>Amakhondomu abesifazane ngawafaka ngendlela engatshelwe ngayo enkomeni yami.</i>)</p> <p><input type="checkbox"/> b. My spouse/partner placed the study condoms in my anus. (<i>Umkhwenyana/uphathina wami wawafaka amakhondomu abesifazane enkomeni yami.</i>)</p> <p><input type="checkbox"/> c. The study condom was inserted into my anus on my partners penis. (<i>Zulu</i>)</p> <p><input type="checkbox"/> d. Other, explain (<i>Okunye, uchaze</i>): _____</p>	
<p><b>10. How easy was it to insert these study condoms?</b> (<i>Kwakulula kangakanani ukufaka lamakhondomu abesifazane ocwaningo?</i>) <b>READ ALL OPTIONS</b></p> <p>1 = Very difficult (<i>Kubukhuni kakhulu</i>) 2 = Difficult, but improved with practice (<i>Kubukhuni kodwa kuba ngcono ngokujwayela</i>) 3 = Easy (<i>Kulula</i>) 4 = Very easy (<i>Kulula kakhulu</i>)</p>	<input style="width: 50px;" type="text"/>



<p><b>11. At any time <u>during sex</u> did <u>any</u> of the study condoms slip some or all of the way out of the anus or move in and out on the partners penis?</b> (<i>check condom log for slippage Q X for any of the condoms used, this Q is additionally probing for any slippage during sex</i>) (Zulu)</p> <p>1 = NO (CHA) → go to Question 12.          2 = YES (YEBO) → go to Question 11.          3 = Unsure (Zulu) → go to Question 13.</p>	<div style="border: 1px solid black; width: 40px; height: 40px; margin: 0 auto;"></div>																														
<p><b>12. For each condom which slipped some or all of the out of the anus or moved in and out on the partners penis please can you give us more detail about what happened?</b></p> <p><b>Mark  X  for all that apply and explain detail below table.</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 50%;">Condom use number (Table to be translated)</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> </thead> <tbody> <tr> <td>The condom slipped partially but not completely out of the anus during sex</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>The condom slipped out of the anus completely during sex</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>The condom seemed to be moving in and out on the penis during sex</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>The condom slipped out onto the penis after he withdrew after sex.</td> <td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table> <p style="margin-top: 10px;">Use this space below to describe the event in more detail if required, noting which condom use the event is referring too.</p> <div style="border-bottom: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 20px; margin-bottom: 5px;"></div>		Condom use number (Table to be translated)	1	2	3	4	5	The condom slipped partially but not completely out of the anus during sex						The condom slipped out of the anus completely during sex						The condom seemed to be moving in and out on the penis during sex						The condom slipped out onto the penis after he withdrew after sex.					
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<p><b>13. For each study condom used can you describe the position of the outer ring/ <u>before you</u> removed it from the anus <u>after sex</u>, compared to the position after it was inserted?</b> (<i>Check condom log for invagination-if unsure how to describe the position, check again if the event happened during or after sex</i>) (Zulu)</p> <p><b>Mark  X  all that apply.</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 50%;">Condom use (Table to be translated)</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> </thead> <tbody> <tr> <td>Outer ring <u>outside</u> the anus, in the same place as when inserted before sex</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>Outer ring <u>outside</u> the anus but some of the condom had moved out further from anus.</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>Outer ring <u>outside</u> the anus but some of the condom had moved further into the anus.</td> <td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>Not sure as my partner/spouse removed the study condom from my anus</td> <td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table>		Condom use (Table to be translated)	1	2	3	4	5	Outer ring <u>outside</u> the anus, in the same place as when inserted before sex						Outer ring <u>outside</u> the anus but some of the condom had moved out further from anus.						Outer ring <u>outside</u> the anus but some of the condom had moved further into the anus.						Not sure as my partner/spouse removed the study condom from my anus					
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	The study condom slipped out on my partner's penis after he withdrew after sex.							
	Not sure/Cannot remember							

**14. Did you remove each of the study condoms from your anus in the same way?** (Wawakhipha ngendlela efanayo yini amakhondomu ebesifazane enkomeni yakho?)

1 = NO (CHA)  
2 = YES (YEBO)

**15. How did you remove the study condoms from the anus?** (Uwakhiphe kanjani enkomeni yakho lamakhondomu abesifazane ocwaningo?)

**Mark ☒ all that apply.**

☐ a. My spouse/partner removed the study condom from my anus. (Umkhwenyana/Uphathina wayifaka ikhondomu yabesifazane enkomeni yami.)

☐ b. I twisted the open end (outer ring) and pulled the study condom out of my anus as instructed. (Ngasonta iringi yangaphandle yekhondomu yabesifazane futhi ngayidonsela ngaphandle enkomeni yami ngokucophelela njengoba ngatshelwa.)

☐ c. I pulled the study condoms straight out of my anus without twisting the condoms. (Ngavele nje ngawadonsela ngaphandle enkomeni yami amakhondomu abesifazane ngaphandle kokuwasonta amakhondomu.)

☐ d. The study condom pulled out on my spouse/partner's penis when he withdrew his penis from my anus. (Ikhondomu yabesifazane yaziphumela yona epipini lika mkhwenyana/phathina wami ngenkathi ekhipha Ipipi lakhe enkomeni yami.)

☐ e. Other, explain (Okunye, uchaze): \_\_\_\_\_

**16. Please rate each feature of this study condom as follows:** (Ngicela ungikalele isakhiwo salekhondomu yabesifazane ngasodwana njengokulandelayo: **Write one number response in every box.** (Bhala Inombolo eyodwa eyimpendulo kuwowonke amabhokiso.) **READ ALL OPTIONS**

**1 = Liked very much** (Ngiyithandile kakhulu)  
**2 = Liked somewhat** (Ngiyithandile ngandlelathize)  
**3 = Neither liked or disliked** (Phakathi kokuyithanda nokungayithandi)  
**4 = Disliked somewhat** (Angiyithandi ndlelathize)  
**5 = Disliked very much** (Angiyithandi kakhulu)  
**6 = Did not notice/no opinion/did not see** (Zulu)

	Feature	Before sex/observation	During sex
a.	Length (Ubude)		
b.	Amount of lubrication (Ubungako bamafutha okugcoba)		
c.	Appearance of condom before insertion (Zulu)		
d.	Appearance after insertion (external feature on body)(Zulu)		
e.	Scent (Iphunga)		

f.	Colour ( <i>Umbala</i> )		
g.	Overall fit inside anus ( <i>Ukulingana kwayo konke</i> )		
h.	Overall fit of ring outside anus (Zulu)		
i.	Feel/sensation ( <i>Ukuzwakala</i> )		

<p><b>17. How did you like using this study condom?</b> (<i>Wakuthanda kanjani ukusebenzisa lekhondomu yabesifazane?</i>) <b>READ ALL OPTIONS</b></p> <p>1 = Liked very much (<i>Ngiyithandile kakhulu</i>)→ <b>Go to Q. 18</b>  2 = Liked somewhat (<i>Ngiyithandile ngandlelathize</i>) → <b>Go to Q. 18</b>  3 = Neither liked nor disliked (<i>Phakathi kokuyithanda nokungayithandi</i>)  4 = Disliked somewhat (<i>Angiyithandi ndlelathize</i>) → <b>Go to Q. 19</b>  5 = Disliked very much (<i>Angiyithandi kakhulu</i>)→ <b>Go to Q. 19</b></p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
<p><b>18. Why did you <u>like</u> using this study condom?</b> (<i>Kungani wathanda ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>19. Why did you <u>dislike</u> using this study condom?</b> (<i>Kungani ungathandanga ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>20. During sex did you feel the study condom was stable (stayed in one place) (Zulu)</b>  1 = NO (any of 5 uses) (<i>CHA</i>)  2 = YES, in every use (<i>YEBO</i>)  If NO, why _____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
<p><b>21. Was this study condom comfortable to use?</b> (<i>Ingabe kwakulula ukusebenzisa lekhondomu yabesifazane?</i>)</p> <p>1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If NO, why _____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
<p><b>22. If you had a choice of using this study condom and a male condom which would you prefer? (Zulu)</b></p> <p>1= Study condom  2= Male condom</p> <p>Please can you briefly explain your choice _____</p> <p>_____</p> <p>_____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
<p><b>23. Would you recommend this study condom to a friend? (Zulu)</b></p> <p>1 = NO (<i>CHA</i>)</p>	

<p>2 = YES (YEBO)</p> <p>If <b>NO</b>, why (<i>Uma uthi cha, kungani?</i>)</p> <p>_____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px;"></div>
<p><b>24. Would you be interested in using this study condom in future? (Zulu)</b></p> <p>1 = NO (CHA)</p> <p>2 = YES (YEBO)</p> <p>If <b>NO</b>, why (<i>Uma uthi cha, kungani?</i>)</p> <p>_____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px;"></div>

## 10.7 Follow-up Survey 2 Female CCC

## FOLLOW-UP VISIT 2 SURVEY

# A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

**12. Study Number:**   O  |  I  |  C  |  1  |  

**13. Participant Number:**   |\_|\_|\_|\_|-|\_|\_|\_|\_|

**14. Date of Interview:**   |\_|\_|/|\_|\_|/|\_|\_|\_|\_| (dd/mm/yyyy)

**4. Interviewer Number:**   |\_|\_|\_|\_|

**5. Follow-up Visit Number:** |\_\_|

**6. Participant Randomization Sequence:** |\_\_\_\_|\_\_\_\_|

<p><b>25. Were the written instructions for how to use this study condom easy to follow?</b>  <i>(Ingabe kwakulula ukulandela imiyalelo eyayibhaliwe yokuthi ungayisebenzisa kanjani lekhondomu yabesifazane?)</i></p> <p>1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If <b>NO</b>, why? (<i>Uma uthi cha kungani?</i>) _____</p>	<div></div>
<p><b>26. Did you insert each study study condom into your vagina the same way every time you used the study condoms?</b> <i>(Ubuwafaka ngendlela efanayo njalo yini lamakhondomu abesifazane ocwaningo enkomeni uma uwasebenzisa?)</i></p> <p>1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)</p>	<div></div>
<p><b>27. How did you insert these study study condoms?</b> <i>(Uwafake kanjani lamakhondomu abesifazane ocwaningo?)</i></p> <p><b>Mark <input checked="" type="checkbox"/> all that apply.</b> <i>(Makha ngo X konke okungenayo.)</i></p> <p><input type="checkbox"/> a. I placed the study condoms in my vagina as instructed. <i>(Amakhondomu abesifazane ngawafaka ngendlela engatshelwe ngayo enkomeni yami.)</i></p> <p><input type="checkbox"/> b. My spouse/partner placed the study condoms in my vagina. <i>(Umkhwenyana/uphathina wami wawafaka amakhondomu abesifazane enkomeni yami.)</i></p> <p><input type="checkbox"/> c. The study condom was inserted into my vagina on my partners penis. <i>( Zulu)</i></p> <p><input type="checkbox"/> d. Other, explain <i>(Okunye, uchaze):</i></p> <p>_____</p>	
<p><b>28. How easy was it to insert these study study condoms?</b> <i>(Kwakulula kangakanani ukufaka lamakhondomu abesifazane ocwaningo?)</i> <b>READ ALL OPTIONS</b></p> <p>1 = Very difficult (<i>Kubukhuni kakhulu</i>)  2 = Difficult, but improved with practice (<i>Kubukhuni kodwa kuba ngcono ngokujwayela</i>)  3 = Easy (<i>Kulula</i>)  4 = Very easy (<i>Kulula kakhulu</i>)</p>	<div></div>

<p><b>29. At any time <u>during sex</u> did <u>any</u> of the study condoms slip some or all of the way out of the vagina or move in and out on the partners penis? (check condom log for slippage Q X for any of the condoms used, this Q is additionally probing for any slippage during sex) (Zulu)</b></p> <p>1=NO (CHA) → go to Question 13.  2=YES (YEBO) → go to Question 12.  3= Unsure (zulu) → go to Question 13.</p>	<div style="border: 1px solid black; width: 50px; height: 30px; margin: 0 auto;"></div>																														
<p><b>30. For each condom which slipped some or all of the out of the vagina or moved in and out on the partners penis please can you give us more detail about what happened? (Zulu, all)</b></p> <p><b>Mark  X  for all that apply and explain below table.</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <th style="width: 50%;">Condom use number</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> <tr> <td>The condom slipped partially but not completely out of my vagina during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom slipped out of my vagina completely during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom seemed to be moving in and out on my partners penis during sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The condom slipped out on my partner's penis after he withdrew after sex.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table> <p><b>Use this space below to describe the event in more detail if required, noting which condom use the event is referring too.</b></p> <div style="border: 1px solid black; height: 150px; margin-top: 10px;"></div>		Condom use number	1	2	3	4	5	The condom slipped partially but not completely out of my vagina during sex						The condom slipped out of my vagina completely during sex						The condom seemed to be moving in and out on my partners penis during sex						The condom slipped out on my partner's penis after he withdrew after sex.					
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<p><b>31. For each study condom used can you describe the position of the outer ring <u>before you</u> removed it from the vagina <u>after sex</u>, compared to the position it was in when you inserted it?</b>  <i>( Check condom log and ask the woman to show the position on the pelvic model if unsure how to describe the position, check again if the event happened during or after sex) (Zulu, all)</i></p> <p><b>Mark  X  all that apply.</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <th style="width: 50%;">Condom use</th> <th style="width: 10%;">1</th> <th style="width: 10%;">2</th> <th style="width: 10%;">3</th> <th style="width: 10%;">4</th> <th style="width: 10%;">5</th> </tr> <tr> <td>Outer ring <u>outside</u> the vagina, in the same place as when inserted and before sex</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Outer ring <u>outside</u> the vagina but some of the condom had moved out further from vagina.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		Condom use	1	2	3	4	5	Outer ring <u>outside</u> the vagina, in the same place as when inserted and before sex						Outer ring <u>outside</u> the vagina but some of the condom had moved out further from vagina.																	
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Outer ring <u>outside</u> the vagina but some of the condom had moved further into the vagina.							
All or part of outer ring <u>inside</u> the vagina (should be marked on condom log)							
Not sure as my partner/spouse removed the study condom from my vagina							
The condom slipped out on my partner's penis after he withdrew after sex.							
Not sure/Cannot remember							

**32. Did you remove each of the study study condoms from your vagina in the same way?** (*Wawakhipha ngendlela efanayo yini amakhondomu ebesifazane enkomeni yakho?*)

1 = NO (*CHA*)  
2 = YES (*YEBO*)

**33. How did you remove the study study condoms from your vagina?** (*Uwakhiphe kanjani enkomeni yakho lamakhondomu abesifazane ocwaningo?*)  
**Mark ☒ all that apply.** (*Makha ngo X konke okungenayo.*)

☐ a. My spouse/partner removed the study condom from my vagina. (*Umkhwenyana/Uphathina wayifaka ikhondomu yabesifazane enkomeni yami.*)

☐ b. I twisted the open end (outer frame) and pulled the study condom out of my vagina as instructed. (*Ngasonta iringi yangaphandle yekhondomu yabesifazane futhi ngayidonsela ngaphandle enkomeni yami ngokucophelela njengoba ngatshelwa.*)

☐ c. I pulled the study condoms straight out of my vagina without twisting the condoms. (*Ngavele nje ngawadonsela ngaphandle enkomeni yami amakhondomu abesifazane ngaphandle kokuwasonta amakhondomu.*)

☐ d. The study condom pulled out on my spouse/partner's penis when he withdrew his penis from my vagina. (*Ikhondomu yabesifazane yaziphumela yona epipini lika mkhwenyana/phathina wami ngenkathi ekhipha Ipipi lakhe enkomeni yami.*)

☐ e. Other, explain (*Okunye, uchaze*): \_\_\_\_\_

**34. Please rate each feature of this study condom as follows:** (*Ngicela ungikalele isakhiwo salekhondomu yabesifazane ngasodwana njengokulandelayo: Write one number response in every box. (Bhala Inombolo eyodwa eyimpendulo kuwowonke amabhokiso.) READ ALL OPTIONS*)

1 = Liked very much (*Ngiyithandile kakhulu*)  
2 = Liked somewhat (*Ngiyithandile ngandlelathize*)  
3 = Neither liked or disliked (*Phakathi kokuyithanda nokungayithandi*)  
4 = Disliked somewhat (*Angiyithandi ndlelathize*)  
5 = Disliked very much (*Angiyithandi kakhulu*)  
6 = Did not notice/no opinion/did not see

	<i>Feature</i>	<i>Before sex/observation</i>	<i>During sex</i>
a.	<i>Length (Ubude)</i>		

b.	Amount of lubrication ( <i>Ubungako bamafutha okugcoba</i> )		
c.	Appearance before insertion ( <i>Ukubukeka</i> )		
d.	Appearance after insertion (external feature on body) ( <i>zulu</i> )	Self  ____  partner ____	
e.	Scent ( <i>Iphunga</i> )		
f.	Colour ( <i>Umbala</i> )		
g.	Overall fit inside vagina ( <i>Ukulingana kwayo konke</i> )		
h.	Overall fit of ring outside vagina ( <i>zulu</i> )		
i.	Feel/sensation ( <i>Ukuzwakala</i> )		

<p><b>35. How did you like using this study condom?</b> (<i>Wakuthanda kanjani ukusebenzisa lekhondomu yabesifazane?</i>) <b>READ ALL OPTIONS</b></p> <p>1 = Liked very much (<i>Ngiyithandile kakhulu</i>) → <b>Go to Q. 18</b>  2 = Liked somewhat (<i>Ngiyithandile ngandlelathize</i>) → <b>Go to Q. 18</b>  3 = Neither liked nor disliked (<i>Phakathi kokuyithanda nokungayithandi</i>)  4 = Disliked somewhat (<i>Angiyithandi ndlelathize</i>) → <b>Go to Q. 19</b>  5 = Disliked very much (<i>Angiyithandi kakhulu</i>) → <b>Go to Q. 19</b></p>	____
<p><b>36. Why did you <u>like</u> using this study condom?</b> (<i>Kungani wathanda ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>37. Why did you <u>dislike</u> using this study condom?</b> (<i>Kungani ungathandanga ukusebenzisa lekhondomu yabesifazane?</i>) _____</p> <p>_____</p>	
<p><b>38. During sex did you feel the condom was stable (stayed in one place) (zulu)</b>  1 = NO (any of 5 uses) (<i>CHA</i>)  2 = YES, in every use (<i>YEBO</i>)  If NO, why _____</p>	____
<p><b>39. Was this study condom comfortable to use?</b> (<i>Ingabe kwakulula ukusebenzisa lekhondomu yabesifazane?</i>)</p> <p>1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If NO, why _____</p>	____
<p><b>40. If you had a choice of using this study condom and a male condom which would you prefer?</b></p> <p>1 = Study condom</p>	____



<p>2= Male condom</p> <p>Please can you briefly explain your choice_____</p> <p>_____</p>																																																																																																							
<p><b>41. Would you recommend this study condom to a friend? (zulu)</b></p> <p>1 = NO (CHA) 2 = YES (YEBO) If <b>NO</b>, why(Uma uthi cha, kungani?)</p> <p>_____</p>	____																																																																																																						
<p><b>42. Would you be interested in using this study condom in future? (zulu)</b></p> <p>1 = NO (CHA) 2 = YES (YEBO) If <b>NO</b>, why(Uma uthi cha, kungani?)</p> <p>_____</p>	____																																																																																																						
<p><b>COMPARISON OF 2 STUDY CONDOMS (UKUQHATHANISWA KWAMAKHONDOMU ABESIFAZANE AMATHATHU)</b></p> <p><b>Show the Participant the 2 types of condoms she has used, <u>in the order that they were used.</u> Refer to the Randomization Sequence. Make sure that you are displaying the correct order.</b></p>																																																																																																							
<p><b>43. For each characteristic or experience mentioned which study condom performed best. (Zulu, all)</b></p> <p><i>As participant responds point to the condom chosen to ensure it is the correct choice</i></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #f2f2f2;"> <th></th> <th>Characteristic or experience</th> <th>Condom F</th> <th>Condom O</th> <th>Both of them</th> <th>Neither of them</th> </tr> </thead> <tbody> <tr><td>1</td><td>Handling the condom</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>2</td><td>Inserting the condom in the vagina</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>3</td><td>Inserting penis into the condom</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>4</td><td>Withdrawing penis from condom</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>5</td><td>Removing the condom from the vagina</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>6</td><td>Comfort wearing the condom</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>7</td><td>General fit of the external part of condom outside the vagina</td><td><input type="checkbox"/><sub>1</sub></td><td><input 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type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	5	Removing the condom from the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	6	Comfort wearing the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	7	General fit of the external part of condom outside the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	8	General fit inside the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	9	Sensation/feeling upon insertion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	10	Sensation during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	11	Stability of condom before sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	12	Stability of condom during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	13	Initial appearance of condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	14	Appearance after insertion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	15	Feel of condom material/texture	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	16	Amount of lubrication on the condom (before any addition)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
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	17	Scent	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	
<b>44. Based on your experience using both condoms in this study, which condom did you like the best overall?</b>  1= Condom F 2= Condom O 3= Liked both the same (no preference) 4= Did not like either of them. 5= Not sure							<input type="text"/>
<b>This is the end of the study. Thank you for your time and commitment to the study.</b>							

## 10.8 Follow-up Survey 2 Males DLGCHC

### FOLLOW-UP VISIT 2 SURVEY A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

15. Study Number:   O  I  C  1  

16. Participant Number:       -      

17. Date of Interview:        /        /        (dd/mm/yyyy)

18. Interviewer Number:       

19. Follow-up Visit Number:       

20. Participant Randomization Sequence:       

<p><b>21. Were the written instructions for how to use this study condom easy to follow?</b> (<i>Ingabe kwakulula ukulandela imiyalelo eyayibhaliwe yokuthi ungayisebenzisa kanjani lekhondomu yabesifazane?</i>)</p> <p>1 = NO (<i>CHA</i>) 2 = YES (<i>YEBO</i>) If NO, why? (<i>Uma uthi cha kungani?</i>) _____</p>	<input style="width: 40px;" type="text"/>
<p><b>22. Did you insert each study condom into your anus the same way every time you used the female condoms?</b> (<i>Ubuwafaka ngendlela efanayo njalo yini lamakhondomu abesifazane ocwaningo enkomeni uma uwasebenzisa?</i>)</p> <p>1 = NO (<i>CHA</i>) 2 = YES (<i>YEBO</i>)</p>	<input style="width: 40px;" type="text"/>
<p><b>23. How did you insert these study condoms?</b> (<i>Uwafake kanjani lamakhondomu abesifazane ocwaningo?</i>)</p> <p><b>Mark <u>X</u> all that apply.</b> (<i>Makha ngo X konke okungenayo.</i>)</p> <p><input type="checkbox"/> a. I placed the condoms in my anus as instructed with ring removed. (<i>Amakhondomu abesifazane ngawafaka ngendlela engatshelwe ngayo enkomeni yami.</i>)</p> <p><input type="checkbox"/> b. My spouse/partner placed the study condoms in my anus. (<i>Umkhwenyana/uphathina wami wawafaka amakhondomu abesifazane enkomeni yami.</i>)</p> <p><input type="checkbox"/> c. The study condom was inserted into my anus on my partners penis. (<i>Zulu</i>)</p> <p><input type="checkbox"/> d. Other, explain (<i>Okunye, uchaze:</i>) _____</p>	
<p><b>24. How easy was it to insert these study condoms?</b> (<i>Kwakulula kangakanani ukufaka lamakhondomu abesifazane ocwaningo?</i>) <b>READ ALL OPTIONS</b></p> <p>1 = Very difficult (<i>Kubukhuni kakhulu</i>) 2 = Difficult, but improved with practice (<i>Kubukhuni kodwa kuba ngcono ngokujwayela</i>) 3 = Easy (<i>Kulula</i>) 4 = Very easy (<i>Kulula kakhulu</i>)</p>	<input style="width: 40px;" type="text"/>
<p><b>25. At any time during sex did any of the study condoms slip some or all of the way out of the anus or move in and out on the partners penis?</b> (<i>check condom log for slippage Q X for any of the condoms used, this Q is additionally probing for any slippage during sex</i>)</p>	<input style="width: 40px;" type="text"/>

- 1 = NO (CHA) → go to Question 12.  
 2 = YES (YEBO) → go to Question 11.  
 3 = Unsure (Zulu) → go to Question 13.

**26. For each condom which slipped some or all of the out of the anus or moved in and out on the partners penis please can you give us more detail about what happened?**

**Mark |X| for all that apply and explain detail below table.**

Condom use number (Table to be translated)	1	2	3	4	5
The condom slipped partially but not completely out of the anus during sex					
The condom slipped out of the anus completely during sex					
The condom seemed to be moving in and out on the penis during sex					
The condom slipped out onto the penis after he withdrew after sex.					

**Use this space below to describe the event in more detail if required, noting which condom use the event is referring too.**

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**27. For each study condom used can you describe the position of the outer ring/ before you removed it from the anus after sex, compared to the position after it was inserted?**

*( Check condom log for invagination-if unsure how to describe the position, check again if the event happened during or after sex) (Zulu)*

**Mark |X| all that apply.**

Condom use (Table to be translated)	1	2	3	4	5
Outer ring <u>outside</u> the anus, in the same place as when inserted before sex					
Outer ring <u>outside</u> the anus but some of the condom had moved out further from anus.					
Outer ring <u>outside</u> the anus but some of the condom had moved further into the anus.					
Not sure as my partner/spouse removed the study condom from my anus					
The study condom slipped out on my partner's penis after he withdrew after sex.					

Not sure/Cannot remember							
--------------------------	--	--	--	--	--	--	--

**28. Did you remove each of the study condoms from your anus in the same way?** (*Wawakhipha ngendlela efanayo yini amakhondomu ebesifazane enkomeni yakho?*)

**1 = NO (CHA)**  
**2 = YES (YEBO)**

**29. How did you remove the study condoms from the anus?** (*Uwakhiphe kanjani enkomeni yakho lamakhondomu abesifazane ocwaningo?*)

**Mark ☒ all that apply.**

☐ a. My spouse/partner removed the study condom from my anus. (*Umkhwenyana/Uphathina wayifaka ikhondomu yabesifazane enkomeni yami.*)

☐ b. I twisted the open end (outer ring) and pulled the study condom out of my anus as instructed. (*Ngasonta iringi yangaphandle yekhondomu yabesifazane futhi ngayidonsela ngaphandle enkomeni yami ngokucophelela njengoba ngatshelwa.*)

☐ c. I pulled the study condoms straight out of my anus without twisting the condoms. (*Ngavele nje ngawadonsela ngaphandle enkomeni yami amakhondomu abesifazane ngaphandle kokuwasonta amakhondomu.*)

☐ d. The study condom pulled out on my spouse/partner's penis when he withdrew his penis from my anus. (*Ikhondomu yabesifazane yaziphumela yona epipini lika mkhwenyana/phathina wami ngenkathi ekhipha Ipipi lakhe enkomeni yami.*)

☐ e. Other, explain (*Okunye, uchaze*): \_\_\_\_\_

**30. Please rate each feature of this study condom as follows:** (*Ngicela ungikalele isakhiwo salekhondomu yabesifazane ngasodwana njengokulandelayo: Write one number response in every box. (Bhala Inombolo eyodwa eyimpendulo kuwowonke amabhokiso.) READ ALL OPTIONS*)

**1 = Liked very much** (*Ngiyithandile kakhulu*)  
**2 = Liked somewhat** (*Ngiyithandile ngandlelathize*)  
**3 = Neither liked or disliked** (*Phakathi kokuyithanda nokungayithandi*)  
**4 = Disliked somewhat** (*Angiyithandi ndlelathize*)  
**5 = Disliked very much** (*Angiyithandi kakhulu*)  
**6 = Did not notice/no opinion/did not see (Zulu)**

	Feature	Before sex/observation	During sex
a.	Length ( <i>Ubude</i> )		
b.	Amount of lubrication ( <i>Ubungako bamafutha okugcoba</i> )		
c.	Appearance of condom before insertion ( <i>Zulu</i> )		
d.	Appearance after insertion (external feature on body)( <i>Zulu</i> )		
e.	Scent ( <i>Iphunga</i> )		
f.	Colour ( <i>Umbala</i> )		
g.	Overall fit inside anus ( <i>Ukulingana kwayo konke</i> )		

	h.	Overall fit of ring outside anus (Zulu)			
	i.	Feel/sensation ( Ukuzwakala)			
<b>31. How did you like using this study condom?</b> ( <i>Wakuthanda kanjani ukusebenzisa lekhondomu yabesifazane?</i> ) <b>READ ALL OPTIONS</b>					<input type="text"/>
1 = Liked very much ( <i>Ngiyithandile kakhulu</i> )→ <b>Go to Q. 18</b> 2 = Liked somewhat ( <i>Ngiyithandile ngandlelathize</i> ) → <b>Go to Q. 18</b> 3 = Neither liked nor disliked ( <i>Phakathi kokuyithanda nokungayithandi</i> ) → <b>Go to Q. 19</b> 4 = Disliked somewhat ( <i>Angiyithandi ndlelathize</i> ) → <b>Go to Q. 19</b> 5 = Disliked very much ( <i>Angiyithandi kakhulu</i> )→ <b>Go to Q. 19</b>					
<b>32. Why did you <u>like</u> using this study condom?</b> ( <i>Kungani wathanda ukusebenzisa lekhondomu yabesifazane?</i> ) _____ _____					
<b>33. Why did you <u>dislike</u> using this study condom?</b> ( <i>Kungani ungathandanga ukusebenzisa lekhondomu yabesifazane?</i> ) _____ _____					
<b>34. During sex did you feel the study condom was stable (stayed in one place) (Zulu)</b> 1 = NO (any of 5 uses) ( <i>CHA</i> ) 2 = YES, in every use ( <i>YEBO</i> ) If <b>NO</b> , why _____					<input type="text"/>
<b>35. Was this study condom comfortable to use?</b> ( <i>Ingabe kwakulula ukusebenzisa lekhondomu yabesifazane?</i> ) 1 = NO ( <i>CHA</i> ) 2 = YES ( <i>YEBO</i> ) If <b>NO</b> , why _____					<input type="text"/>
<b>36. If you had a choice of using this study condom and a male condom which would you prefer? (Zulu)</b> 1= Study condom 2= Male condom Please can you briefly explain your choice _____ _____ _____					<input type="text"/>
<b>37. Would you recommend this study condom to a friend? (Zulu)</b> 1 = NO ( <i>CHA</i> ) 2 = YES ( <i>YEBO</i> ) If <b>NO</b> , why ( <i>Uma uthi cha, kungani?</i> ) _____ _____					<input type="text"/>

<p><b>38. Would you be interested in using this study condom in future? (Zulu)</b></p> <p>1 = NO (CHA)          2 = YES (YEBO)          If <b>NO</b>, why (<i>Uma uthi cha, kungani?</i>)</p> <p>_____</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>																																																																																																												
<p><b>39. For each characteristic or experience mentioned which study condom performed best. (Zulu, all)</b></p> <p><i>As participant responds point to the condom chosen to ensure it is the correct choice</i></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #f2f2f2;"> <th style="width: 5%;"></th> <th style="width: 40%;">Characteristic or experience</th> <th style="width: 15%;">Condom F</th> <th style="width: 15%;">Condom O</th> <th style="width: 15%;">Both of them</th> <th style="width: 15%;">Neither of them</th> </tr> </thead> <tbody> <tr><td>1</td><td>Handling the condom</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> <tr><td>2</td><td>Inserting the condom in the anus</td><td><input type="checkbox"/><sub>1</sub></td><td><input type="checkbox"/><sub>2</sub></td><td><input type="checkbox"/><sub>3</sub></td><td><input type="checkbox"/><sub>4</sub></td></tr> 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type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	3	Inserting penis into the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	4	Withdrawing penis from condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	5	Removing the condom from the anus	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	6	Comfort wearing the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	7	General fit of the external part of condom outside the anus	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	8	General fit inside the anus	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	9	Sensation upon insertion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	10	Sensation during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	11	Stability of condom before sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	12	Stability of condom during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	13	Initial appearance of condom	<input type="checkbox"/> 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<p><b>40. Based on your experience using both condoms in this study, which condom did you like the best overall?</b></p> <p>1= Condom F          2=Condom O          3= Liked both the same (no preference)          4=Did not like either of them.          5= Not sure</p>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>																																																																																																												
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## 10.9 Male Partner of Females- Follow-up Survey CCC

### MALE FOLLOW-UP SURVEY A Randomized Crossover Trial of The Functional Performance, Safety and Acceptability of the Origami Internal Condom.

41. Study Number:   O  I  C  1
42. Participant Number:       -
43. Date of Interview:        /        /        (dd/mm/yyyy)
4. Interviewer Number:
5. Follow-up Visit Number:
6. Participant Randomization Sequence:

1. Please rate each feature of this study condom as follows: (*Ngicela ungikalele isakhiwo salekhondomu yabesifazane ngasodwana njengokulandelayo: Write one number response in every box. (Bhala Inombolo eyodwa eyimpendulo kuwowonke amabhokiso.) READ ALL OPTIONS*)

- 1 = Liked very much (*Ngiyithandile kakhulu*)  
 2 = Liked somewhat (*Ngiyithandile ngandlelathize*)  
 3 = Neither liked or disliked (*Phakathi kokuyithanda nokungayithandi*)  
 4 = Disliked somewhat (*Angiyithandi ndlelathize*)  
 5 = Disliked very much (*Angiyithandi kakhulu*)  
 6 = Did not notice/no opinion/did not see

	Feature	Before sex/observation	During sex
a.	Length ( <i>Ubude</i> )		
b.	Amount of lubrication ( <i>Ubungako bamafutha okugcoba</i> )		
c.	Appearance before insertion ( <i>Ukubukeka</i> )		
d.	Appearance after insertion (external feature on body) ( <i>zulu</i> )		
e.	Scent ( <i>Iphunga</i> )		
f.	Colour ( <i>Umbala</i> )		
g.	Overall fit inside vagina ( <i>Ukulingana kwayo konke</i> )		
h.	Overall fit of ring outside vagina ( <i>zulu</i> )		
i.	Feel/sensation ( <i>Ukuzwakala</i> )		

2. How did you like using this study condom? (*Wakuthanda kanjani ukusebenzisa lekhondomu yabesifazane?*) **READ ALL OPTIONS**

- 1 = Liked very much (*Ngiyithandile kakhulu*) → **Go to Q. 18**  
 2 = Liked somewhat (*Ngiyithandile ngandlelathize*) → **Go to Q. 18**  
 3 = Neither liked nor disliked (*Phakathi kokuyithanda nokungayithandi*)



<p>4 = Disliked somewhat (<i>Angiyithandi ndlelathize</i>) → <b>Go to Q. 19</b>  5 = Disliked very much (<i>Angiyithandi kakhulu</i>)→ <b>Go to Q. 19</b></p>	
<p><b>3. Why did you <u>like</u> using this study condom?</b> (<i>Kungani wathanda ukusebenzisa lekhondomu yabesifazane?</i>) _____  _____</p>	
<p><b>4. Why did you <u>dislike</u> using this study condom?</b> (<i>Kungani ungathandanga ukusebenzisa lekhondomu yabesifazane?</i>) _____  _____</p>	
<p><b>5. During sex did you feel the condom was stable (stayed in one place) (zulu)</b>  1 = NO (any of 5 uses) (<i>CHA</i>)  2 = YES, in every use (<i>YEBO</i>)  If <b>NO</b>, why _____  _____</p>	<p>_____</p>
<p><b>6. Was this study condom comfortable to use?</b> (<i>Ingabe kwakulula ukusebenzisa lekhondomu yabesifazane?</i>)   1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If <b>NO</b>, why _____  _____</p>	<p>_____</p>
<p><b>7. If you had a choice of using this study condom and a male condom which would you prefer?</b>   1= Study condom  2= Male condom   Please can you briefly explain your choice _____  _____</p>	<p>_____</p>
<p><b>8. Would you recommend this study condom to a friend? (zulu)</b>   1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If <b>NO</b>, why(<i>Uma uthi cha, kungani?</i>) _____  _____</p>	<p>_____</p>
<p><b>9. Would you be interested in using this study condom in future? (zulu)</b>   1 = NO (<i>CHA</i>)  2 = YES (<i>YEBO</i>)  If <b>NO</b>, why(<i>Uma uthi cha, kungani?</i>) _____  _____</p>	<p>_____</p>

**COMPARISON OF 2 STUDY CONDOMS (UKUQHATHANISWA KWAMAKHONDOMU ABESIFAZANE AMATHATHU)**

**Show/explain verbally to the Participant the 2 types of condoms he has used, in the order that they were used. Refer to the Randomization Sequence. Make sure that you are displaying/describing the correct order.**

**10. For each characteristic or experience mentioned which study condom performed best. (Zulu, all)**

*As participant responds point to the condom chosen to ensure it is the correct choice (if this is done telephonically, confirm the choice with the participant)*

	Characteristic or experience	Condom F	Condom O	Both of them	Neither of them
1	Handling the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
2	Inserting the condom in the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
3	Inserting penis into the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
4	Withdrawing penis from condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
5	Removing the condom from the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
6	Comfort wearing the condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
7	General fit of the external part of condom outside the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
8	General fit inside the vagina	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
9	Sensation/feeling upon insertion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
10	Sensation during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
11	Stability of condom before sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
12	Stability of condom during sex	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
13	Initial appearance of condom	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
14	Appearance after insertion	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
15	Feel of condom material/texture	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
16	Amount of lubrication on the condom (before any addition)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>
17	Scent	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>

**11. Based on your experience using both condoms in this study, which condom did you like the best overall?**

1= Condom F  
2= Condom O  
3= Liked both the same (no preference)  
4=Did not like either of them.  
5= Not sure

**This is the end of the study. Thank you for your time and commitment to the study.**