Supplementary appendix

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ShangRing versus Mogen clamp for early infant male circumcision in eastern sub-Saharan Africa: a multicentre, non-inferiority, adaptive, randomised controlled trial

Supplementary Material
Evaluation of the ShangRing vs. Mogen Clamp for Early Infant Male Circumcision in sub-Saharan Africa

Statistical Analysis Plan

Phase I

Safety and Acceptability of the no-flip ShangRing Technique vs. Mogen Clamp

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1.0 Study summary

The study is to evaluate the safety effectiveness and acceptability of the ShangRing device for early infant male circumcision (EIMC). The study will be conducted in two phases:

- Phase 1 is to randomize approximately 1360 eligible infants 1:1 to receive either ShangRing or Mogen Clamp circumcision. The Mogen Clamp is one of the EIMC devices included in the WHO training materials for EIMC and is considered the control procedure for this trial. Circumcisions will be conducted by physicians and non-physicians. Assessments of interest are circumcision time, pain, adverse events (AEs), healing course, and parent and provider preferences.

- Phase 2 is a non-comparative field study and will enroll approximately 1800 eligible infants who will undergo ShangRing EIMC performed in routine settings. Surgical outcomes will be similar to the first phase. This is a non-comparative field study.

Participants will be enrolled at 12 sites across Kenya(x3), Tanzania(x4), and Uganda(x5). The study population will include male infants ≤60 days old.

The study being conducted by Weill Cornell Medicine in conjunction with the Population Council, Jhpiego, the Rakai Health Sciences Program, Johns Hopkins University, George Washington University, and the Uganda Virus Research Institute.

This Statistical Analysis Plan is for Phase 1 of the study. Another data analysis plan will be developed for Phase 2.

1.1 Objectives & Endpoints for Phase 1

1.1.1 Primary objective and endpoints
Evaluate the safety and acceptability of the no-flip ShangRing Technique vs, Mogen clamp for EIMC in patients up to 60 days old when used by physicians and non-physicians. The primary endpoint is the rate of AEs following EIMC conducted by physicians and medical providers (non-physician). Other safety endpoints include documentation of time to complete clinical wound healing, device-related malfunctions, and occurrence of device displacement.

1.1.2 Secondary Objectives and endpoints
- Assess ease of use of the ShangRing for EIMC, which will be determined by procedure time and problems encountered during the procedure
- Evaluate satisfaction of ShangRing EIMC among parents of study participants, which will be determined by parent interviews to document acceptability and satisfaction with the ShangRing circumcision as well as procedure and post-procedure pain
- Evaluate satisfaction of using the ShangRing for EIMC among VMMC providers-to document experiences with the use of the ShangRing, problems encountered during medical procedures, and preference of VMMC technique
- Determine the occurrence and safety of spontaneous detachment, which will be determined with data on the timing of spontaneous detachment and documentation of AEs and time course of complete
1.2 Sample Size Justification
The goal is to determine if the AE rate using the ShangRing is not inferior to that for the control (i.e., the Mogen clamp). The anticipated moderate-severe AE rate is 2% for the Mogen clamp control arm. We expect that the benefits of the ShangRing in terms of convenience and acceptability will allow a non-inferiority margin of 2% (absolute). The total sample size combining all three countries of at least 1200 evaluable infants (600 per arm), with one formal interim analysis for futility has approximately 80% power with a (one-sided) alpha = 0.05. The null hypothesis of the non-inferiority test is that the moderate/adverse AE rate for the ShangRing is at least 2% (absolute) higher than that of Mogen clamp, which is assumed to be 2%. The alternative hypothesis is that the moderate/severe adverse event rate of the ShangRing is less than 2% greater than that of the Mogen clamp.

1.3 Electronic Case Reporting Forms
The first stage of data management is the development of the electronic case report forms (eCRFs) using finalized word versions of the case report forms. A total of 10 eCRFs have been developed to capture a wide range of information as follows:

1. Screening visit (DAY 0-SCREEN): This form records screening information and responses to inclusion/exclusion criteria for the study. This form is filled on Day 0
2. Participant demographic data (DAY 0-DEMO): This form records demographic data of the participants. This form is filled on Day 0
3. History and examination (DAY 0-INTAKE): This form collects the medical history of the participant and includes the screening questions to determine eligibility for the study and VMMC. This form is filled on Day 0
4. Operation (DAY 0-OPR): This form gives a record of the operation procedures in the circumcision process and the time taken to perform the surgery. It included information on the participant’s random assignment. This form is filled on Day 0
5. Master participant follow-up form (MPFU): This form is used to gather information during all follow-up visits (scheduled and unscheduled), including information on the removal, status of the wound, and any symptoms of the adverse event. This form includes information on AE, SAEs, and concomitant medication. This form is filled on day 7 and beyond.
6. Post-operation (DAY 0-POST-OPR): This form is used to gather information during the post-op period, including any AEs or medications given.
7. 24hr Call Interview: This form provides information about the status of the infant on POD 1 via phone call to parent/LAR.
8. Completion interview (IVW): This form is used during the interview at the final follow-up visit, which occurs when the participant is determined to be healed.
9. Social Harm Event (SHE): This form documents any social harm event experienced by the participants during the study.

10. Protocol Violated Form (PVF): This form describes any protocols violated during the study. This form is filled on the occurrence of PV

11. Final status form (FINAL): This form is completed to document when the participant leaves the study (i.e., completes follow-up, is discontinued, is declared lost to follow-up)

12. Query Response (QUERY). This form is filled to make corrections in the database.

The key features of the eCRFs are:
- Data validation checks
- Programmed skip patterns
- Pages customized according to individuals’ tasks (e.g., nurse, doctor, etc.)
- Limits (e.g., text, numbers)
- Radio buttons (i.e., prompts to trigger clinicians to ask or look for specific things)

The eCRFs will undergo a series of tests before data collection to ensure they are all correct prior to the start of actual data collection.

1.4 Data collection using the eCRFs

A high level of confidentiality will be strictly adhered to in handling study data from the sites. The site’s unique identification code and participant number will be used to identify each record in an electronic format. The study team will also use in-build provider identifiers for each record to enhance the audit trail of data if needed. The team at the study site will only enter study data for the participants.

Site data will be collected using Open Data Kit (ODK) and a computer tablet. ODK allows for 256-bit encrypted data collection forms, a mechanism for keeping data private after collection and during transit from the respective facilities to a secure server. Encrypted forms apply asymmetric public key encryption at the time the form is finalized within the ODK Collect module. This encrypted form can then be submitted up to the ODK Aggregate module and downloaded to the ODK Briefcase module. ODK Briefcase, when supplied with the asymmetric private key (which ODK Briefcase never stores), can then decrypt and export the form data as a CSV file for analysis and uploading to other servers by key study personnel.

ODK Aggregate cannot meaningfully publish encrypted forms to Google Spreadsheets or Fusion Tables since the encryption obscures the entire contents of the form, and ODK Aggregate never possesses the asymmetric key required to decrypt the form. When using encrypted forms, ODK Aggregate serves only as a data aggregation point — one must download, decrypt, and export the data using ODK Briefcase to access the unencrypted data.

All data collected using the tablet will be coded by Participant Unique ID and will not be accessible to anyone not affiliated with the research project. The field staff will not be able to access the completed interview file from the tablet. These security features will be utilized in order to provide the highest assurances to study participants that their responses will not later be available to the field study staff, and can only be accessed in the central study database by authorized personnel using the asymmetric private key.
Standardized Operating Procedures (SOPs) with resources and mechanisms for data synchronization to the aggregate server, cleaning/editing, and data entry preparation will be used to review data consistency checks and maintain the quality and integrity of the data accumulated. Quality assurance will be supported by examining patterns of missing data to correct any problems found.

1.4.1 Correcting data uploaded to the aggregate server
Data stored in the ODK Aggregate server is read-only and cannot be changed. Measures will be taken to ensure an audit trail of all changes made to the exported eCRFs. A Query Response eCRF will be filled by site study staff or any other authorized person to document changes made to the already uploaded data. The Query Response CRF (Annex 1) will have the participant’s ID updated in the format “SFC/DDMMYY/Participant ID” input.

1.4.2 Data security
To enhance the level of data security, the ODK Aggregate server will have restricted access. A “Data Collect” account will be configured on the tablets used for data collection. This account has restricted rights on the Aggregate server and can only be used to upload collected data. Exported eCRFs will be downloaded to a USB drive and physically stored in a secure cabinet. All tablets used to collect data will have an access code/pattern to restrict access by unauthorized users. Transmission of data form the tablet to the Aggregate server will be over an encrypted connection over the internet.

1.5 Data confidentiality
All study staff will adhere to the highest level of confidentiality when handling study data as per the study protocol and the relevant code of ethics in research studies. All data exchange on e-mail will be password protected.

1.6 Data backup
A weekly, monthly, and completed study period of data backup plan will be enforced. The cloud real-time data backup will be performed daily and also save it on a USB drive, then data backup will be saved on CDROM drives. The backup storage will adhere to data security standards.

1.7 Summary of Analysis Strategy

| Overall analysis strategy | Majorly descriptive | The analysis will be done to establish outcomes of each procedure (ShangRing and Mogen Clamp) and the relationship to the study site. |
|--------------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Study population         | Treatment group     | The analysis will ensure that the comparison of the results obtained from the treatment groups is obtained. The two groups are the ShangRing and Mogen clamp (control arm) |
|                          | Study site          | The analysis will capture the specific outcomes of each of the sites in the three countries (Kenya, Tanzania, and Uganda).     |
| Missing Data             |                      | - Queries will be sent to the site when missing data are identified in the database. To the extent, possible corrections to the database will be made before it is closed.  
                          |                      | - No missing data will be imputed.                                                                                         |
### Inclusion/exclusion criteria

**Inclusion**
- As defined by the study protocol
- All clients screened will form initial analysis to ascertain the eligibility of clients
- The final analysis will encompass clients satisfying inclusion criteria who were randomized.

**Exclusion criteria**
- As defined by the protocol
- The analysis will highlight any case where there was a deviation from the study protocol.

### Reporting conventions

**Data analysis and reporting**
- Absolute numbers will be reported: count, means, standard deviations, maximum, and minimum.
- Proportions will be reported to one decimal place.

**Test of significance**
- Continuous data will be compared using a two-sample t-test
- Proportions will be compared using a chi-square test, or Fisher’s exact test if the assumptions of the chi-square test are violated

**Outliers**
- The use of data validation in data entry into eCRFs will reduce incidences of outliers.
- Outliers identified in the database will be verified by sending queries to the study sites.

### 1.7.1 Final analysis

The final analysis and a report will be prepared upon completion of Phase 1 and will encompass all the indicators captured in the CRFs for those participants randomized during the study. The CSV files for each form will be read into R and then analysed. Table shells and listings are in Section 4.

The analysis will encompass all the quantitative data and qualitative data captured through the CRFs, which will include but not be limited to:

**Demographic Data:** Analysis will be done of the age, ethnic groups, level of education, and religion, etc. of the study participants

**Medical history / physical exam:** Analysis will be done for the participants’ temperature, blood pressure (BP), the heartbeats per minute (BPM), height (ht), weight (wt) etc. at specific time intervals.

**Summary of circumcision procedure:** The analysis will be done for procedure time, amount of anaesthesia used, and ring sizes that were used. Problems encountered during the circumcision procedures will be descriptively summarized in a listing.

**ShangRing removal and detachment:** The average time taken during ring removal will be calculated. Numbers of participants with problems encountered during the removal procedures will be reported with specifics descriptively summarized in a listing. The degree of detachment of the ring from the skin will be analyzed. Issues around spontaneous detachment will include mean and median time to spontaneous detachment, the association between age and time to spontaneous detachment, the association between the comfort of clients and mode of detachment, experience/satisfaction among participants in the two groups, including requested early removal.

**Adverse Events:** For safety, clinical observations for adverse events during the course of wound healing will be analyzed. Adverse events will be reviewed on an ongoing basis during the study to determine any patterns in type, severity etc. that would suggest a problem that needs to be addressed. It will also indicate if the study
should be stopped due to safety concerns. The frequency and percentage of men with procedure-related AEs will be tabulated by severity, both overall and by the site. Listings of AEs will include information on duration, outcome, severity, and relation to study procedures. Listings of any serious adverse events will also be provided.
## 2.0 Final analysis table shells

### 2.1 Enrollment & final status

#### 1a. Enrollment

| Enrolled patients | ShangRing n (%) | Mogen Clamp n (%) | Total |
|-------------------|----------------|------------------|-------|
| Enrolment by country |               |                  |       |
| 1. UGANDA |                 |                  |       |
| 2. TANZANIA |                 |                  |       |
| 3. KENYA |                 |                  |       |

#### Reasons participants not enrolled by site:

| Reason* | n (%) |
|---------|-------|

#### Reasons participants not enrolled by randomization group:

| Reason | ShangRing N (%) | Mogen Clamp |
|--------|-----------------|-------------|

*Each patient was assigned one reason only. The reason assigned was the first reached in the list.

#### 1b. Final study status grand totals – intention to treat population, n (%)

| Comments | ShangRing | Mogen Clamp | Total |
|----------|-----------|-------------|-------|
| Discontinued |           |             |       |
| Lost to follow-up |         |             |       |
| Lost before ring removal or detachment documented |  |
| Complete study $^1$ |  |
| Healed before or at 42 days |  |
| Required additional FU beyond 42 days |  |
| **Total** |  |

$^1$ attended follow-up through documented healing or 42 days.
| Final study status                                    | ShangRing | Mogen Clamp | Total |
|------------------------------------------------------|-----------|-------------|-------|
| Discontinued                                         |           |             |       |
| Lost to follow-up                                    |           |             |       |
| Lost before ring removal or detachment documented    |           |             |       |
| Completed study \(^1\)                               |           |             |       |
| Healed before or at 42 days                          |           |             |       |
| Required additional FU beyond 42 days                |           |             |       |
| Total                                                |           |             |       |
| Study visit completed                                |           |             |       |
| Day 7                                                |           |             |       |
| Day 14                                               |           |             |       |
| Day 21                                               |           |             |       |
| Day 28                                               |           |             |       |
| Day 35                                               |           |             |       |
| Day 42                                               |           |             |       |
| Post-study Visit Day 49                              |           |             |       |
| Post-study Visit Day 56                              |           |             |       |
| Post-study visit day 63                              |           |             |       |
| Unscheduled visits \(^3\)                            |           |             |       |
| 0                                                    |           |             |       |
| 1                                                    |           |             |       |
| 2 (etc as needed)                                    |           |             |       |
| Total                                                |           |             |       |

\(^1\) attended follow-up through documented healing or 42 days.
### 1d. Reason for Unscheduled Visit (from MPFU), n (%)

|                     | ShangRing | Mogen Clamp | Total |
|---------------------|-----------|-------------|-------|
| AE                  |           |             |       |
| The client requested ring removal |         |             |       |
| Other (specify)     |           |             |       |

### 1e. Participant’s reason for withdrawal or discontinuation

|                                   | ShangRing | Mogen Clamp | Total |
|-----------------------------------|-----------|-------------|-------|
| Not eligible (screening failure)  |           |             |       |
| Specify Reason                    |           |             |       |
| Eligible, not enrolled            |           |             |       |
| Specify Reason                    |           |             |       |
| Discontinued/withdrawal           |           |             |       |
| Specify Reason                    |           |             |       |
### 2.2 Demographic Information

#### 2a. Age (days)

| Age Group:          | ShangRing | Mogen Clamp | Total |
|---------------------|-----------|-------------|-------|
| Mean (SD)           |           |             |       |
| Median (Interquartile Range) |           |             |       |
| Range (Min to Max)  |           |             |       |
| ≤ 7 days            |           |             |       |
| 8-14 days           |           |             |       |
| 15-21 days          |           |             |       |
| 22-28 days          |           |             |       |
| 29-35 days          |           |             |       |
| 36-42 days          |           |             |       |
| 43-49 days          |           |             |       |
| 50-56 days          |           |             |       |
| 57-60 days          |           |             |       |

#### 2b. Relationship of the participant to parent/LAR, n (%)

| Relationship          | ShangRing | Mogen Clamp | Total |
|-----------------------|-----------|-------------|-------|
| Father                |           |             |       |
| Mother                |           |             |       |
| Sibling               |           |             |       |
| Guardian              |           |             |       |
| Other (specify)       |           |             |       |
### 2c. Age of Parent/LAR (days)

|                    | ShangRing | Mogen Clamp | Total |
|--------------------|-----------|-------------|-------|
| Mean (SD)          |           |             |       |
| Median (Interquartile Range) | |             |       |
| Range (Min to Max) |           |             |       |

### 2d. Marital Status

|                 | ShangRing | Mogen Clamp | Total |
|-----------------|-----------|-------------|-------|
| Cohabiting      |           |             |       |
| Divorced        |           |             |       |
| Married         |           |             |       |
| Single, never married | |             |       |
| Single, separated |         |             |       |
| Other           |           |             |       |
### 2e. Parent/LAR’s highest level of academic education, n (%)

|                                    | ShangRing | Mogen Clamp | Total |
|------------------------------------|-----------|-------------|-------|
| No formal education                |           |             |       |
| Some Primary                       |           |             |       |
| Completed Primary                  |           |             |       |
| Some Secondary                     |           |             |       |
| Completed Secondary                |           |             |       |
| Some University/College/           |           |             |       |
| Polytechnic                        |           |             |       |
| Completed University/College/      |           |             |       |
| Polytechnic                        |           |             |       |
| Postgraduate                       |           |             |       |
| Other, specify                     |           |             |       |

### 2f. Parent/LAR’s religion, n (%)

|                                    | ShangRing | Mogen Clamp | Total |
|------------------------------------|-----------|-------------|-------|
| Roman Catholic                     |           |             |       |
| Anglican                           |           |             |       |
| Pentecostal                         |           |             |       |
| Seventh-Day Adventist              |           |             |       |
| Muslim                             |           |             |       |
| Hindu                              |           |             |       |
| Nomiya                             |           |             |       |
| African Independent Church         |           |             |       |
| No Religion                        |           |             |       |
| Other (Specify)                    |           |             |       |
## 2g. Ethnic Group of the parent/LAR, n (%)

| Ethnic Group | ShangRing | Mogen Clamp | Total |
|--------------|-----------|-------------|-------|
| Luo          |           |             |       |
| Kisii        |           |             |       |
| Luhya        |           |             |       |
| Teso         |           |             |       |
| Giriama      |           |             |       |
| Taita        |           |             |       |
| Kikuyu       |           |             |       |
| Kamba        |           |             |       |
| Other Specify|           |             |       |

## 2h. Primary Reasons for parent/LAR seeking circumcision for client, n (%)

| Reason                        | ShangRing | Mogen Clamp | Total |
|-------------------------------|-----------|-------------|-------|
| HIV Protection                |           |             |       |
| Hygiene                       |           |             |       |
| As part of medical therapy    |           |             |       |
| Social/religious              |           |             |       |
| Cultural                      |           |             |       |
| Other (specify)               |           |             |       |
| Blank                         |           |             |       |
### 2.3 Intake

#### 2.3.1 Client’s HIV Status

| 3a. HIV status, n (%)          | ShangRing | Mogen Clamp | Total |
|--------------------------------|-----------|-------------|-------|
| HIV negative                   |           |             |       |
| HIV positive                   |           |             |       |
| Tested but does not want to disclose |           |             |       |
| Not tested                     |           |             |       |
### 2.3.2 Vital Signs & Weight

#### 3b. Vital signs

|                        | ShangRing | Mogen Clamp | Total |
|------------------------|-----------|-------------|-------|
| **Heart rate (beats/Min)** |           |             |       |
| Mean (SD)              |           |             |       |
| Min-Max                |           |             |       |
| **Temperature (°C)**   |           |             |       |
| Mean (SD)              |           |             |       |
| Min-Max                |           |             |       |
| **Height (cm)**        |           |             |       |
| Mean (SD)              |           |             |       |
| Min-Max                |           |             |       |
| **Weight (Kgs)**       |           |             |       |
| Mean (SD)              |           |             |       |
| Min-Max                |           |             |       |
| **Respiratory rate (breaths/min)** |       |             |       |
| Mean (SD)              |           |             |       |
| Min-Max                |           |             |       |
### 2.3.3 Client History

#### 3c. Site of delivery for infant, n (%)

|                  | ShangRing | Mogen Clamp | Total |
|------------------|-----------|-------------|-------|
| Home             |           |             |       |
| Facility         |           |             |       |
| Other (specify)  |           |             |       |

#### 3d. Mode of delivery, n (%)

|                                              | ShangRing | Mogen Clamp | Total |
|----------------------------------------------|-----------|-------------|-------|
| Spontaneous vaginal delivery                 |           |             |       |
| Assisted delivery (specify)                  |           |             |       |
| Caesarean section                            |           |             |       |

#### 3e. Parent has history of or undergoing treatment for illnesses, n (%)

|                                                      | ShangRing | Mogen Clamp | Total |
|-------------------------------------------------------|-----------|-------------|-------|
| Hemophilia or other bleeding disorder                 |           |             |       |
| Diabetes                                              |           |             |       |
| Anemia                                                |           |             |       |
| Sickle cell                                           |           |             |       |
| Other (specify)                                       |           |             |       |

#### 3f. Current conditions: Infant presenting with any of the listed conditions/complaints, n (%)

|                                             | ShangRing | Mogen Clamp | Total |
|---------------------------------------------|-----------|-------------|-------|
| Fever                                       |           |             |       |
| Genital sore (ulcer)                        |           |             |       |
| Jaundice                                    |           |             |       |
| Urethral discharge                          |           |             |       |
| Swelling of the scrotum                     |           |             |       |
| Other (specified)                           |           |             |       |
3g. Participants have any known allergies, n (%)

|       | ShangRing | Mogen Clamp | Total |
|-------|-----------|-------------|-------|
| Yes   |           |             |       |
| No    |           |             |       |

3h. Known allergy description

| Country | Study Arm | Allergy description | Manifestation | Treatment if known | n |
|---------|-----------|---------------------|---------------|--------------------|---|
|         |           |                     |               |                    |   |

3i. Participants ever had the surgical operation, n (%)

|       | ShangRing | Mogen Clamp | Total |
|-------|-----------|-------------|-------|
| Yes (specify) |           |             |       |
| No    |           |             |       |
## 2.4 Eligibility for Circumcision & Study

### 4a. Inclusion/Exclusion criteria, n (%)

| INCLUSION (all should be 100%)                                                                 | ShangRing | Mogen Clamp | Total |
|------------------------------------------------------------------------------------------------|-----------|-------------|-------|
| 60 days or younger                                                                           |           |             |       |
| Birth weight ≥2.5kg                                                                          |           |             |       |
| Gestational age ≥37 weeks                                                                     |           |             |       |
| Uncircumcised with a fully intact foreskin                                                     |           |             |       |
| In good general health                                                                        |           |             |       |
| Free of genital ulcerations/infections                                                        |           |             |       |
| Parent(s)/LAR understand all study procedures and requirements                               |           |             |       |
| Parent(s)/LAR agree to return the participant for all follow-up visits                       |           |             |       |
| Parent(s)/LAR have a cellphone or access to a cellphone                                       |           |             |       |
| Parent(s)/LAR agree to provide an address, phone number or other locator information while participating in the study |           |             |       |

### EXCLUSION (all should be 0%)

| EXCLUSION (all should be 0%)                                                                 | ShangRing | Mogen Clamp | Total |
|------------------------------------------------------------------------------------------------|-----------|-------------|-------|
| Have known allergy to lidocaine/other local anesthesia                                        |           |             |       |
| Have an active genital infection, anatomic abnormality or other condition that prevents him from undergoing a circumcision |           |             |       |
| On blood thinners, steroids, or other medications that may preclude him                      |           |             |       |
| Reason                                                                 | ShangRing | Mogen Clamp | Total |
|------------------------------------------------------------------------|-----------|-------------|-------|
| from normal wound healing/have a family history of bleeding disorders  |           |             |       |
| Have a condition that contradicts participation in the study           |           |             |       |
| currently participating in another biomedical research study           |           |             |       |

4b. Eligibility

| Eligible for study, n (%) | ShangRing | Mogen Clamp | Total |
|---------------------------|-----------|-------------|-------|
| Reasons for those not eligible |           |             |       |
| Reason 1                  |           |             |       |
| Reason 2                  |           |             |       |
| Reason 3                  |           |             |       |

| Otherwise medically eligible for ShangRing circumcision, n (%) | ShangRing | Mogen Clamp | Total |
|---------------------------------------------------------------|-----------|-------------|-------|
| Reasons for those not eligible                               |           |             |       |
| Reason 1                                                      |           |             |       |
| Reason 2                                                      |           |             |       |
| Reason 3                                                      |           |             |       |

| Would be eligible for conventional circumcision, n (%) | ShangRing | Mogen Clamp | Total |
|-------------------------------------------------------|-----------|-------------|-------|
| Reasons for those not eligible                         |           |             |       |
| Reason 1                                               |           |             |       |
| Reason 2                                               |           |             |       |
| Reason 3                                               |           |             |       |
2.5 Operation

| 5a. Was there need to supplement topical anesthesia with injectable anesthesia before the start of the procedure? |
|---------------------------------------------------------------|
|                                                               |
|                                                               |
| **ShangRing** | **Mogen Clamp** | **Total** |
| Yes            |                |           |
| No             |                |           |

| 5b. NIPS pain score immediately prior to circumcision |
|------------------------------------------------------|
|                                                      |
| **ShangRing** | **Mogen Clamp** | **Total** |
| Facial expression | Relaxed | Grimacing |
|                   | No Cry    |           |
|                   | Whimper   |           |
|                   | Vigorous cry |       |
| Breathing Pattern | Relaxed | Change in breathing |
|                   | Restraised or Relaxed |      |
|                   | Flexed or Extended |      |
| Arms             |             |           |
|                   | Restraised or Relaxed |      |
|                   | Flexed or Extended |      |
| Legs             |             |           |
|                   | Restraised or Relaxed |      |
|                   | Flexed or Extended |      |
| State of arousal | Sleeping or Awake |       |
|                   | Fussy      |           |
| Total NIPS score |          |           |
| Mean (SD)        |          |           |
| Min-Max          |          |           |
| 5c. Adhesions, n (%) | ShangRing | Mogen Clamp | Total |
|----------------------|-----------|-------------|-------|
| Necessary to break down adhesions between the foreskin and head of the penis |           |             |       |
| Degree of adhesions (among those where adhesions has to be broken down) |           |             |       |
| Mild                 |           |             |       |
| Moderate             |           |             |       |
| Severe               |           |             |       |
5d. Circumcision procedure duration in minutes

|                      | ShangRing | Mogen Clamp | Total |
|----------------------|-----------|-------------|-------|
| Mean duration (in min)|           |             |       |
| SD                   |           |             |       |
| Median (IQR)         |           |             |       |
| Max                  |           |             |       |
| Min                  |           |             |       |
| Outliers             |           |             |       |

5e. Type of circumcision procedure conducted, n (%)

|                      | ShangRing | Mogen Clamp | Total |
|----------------------|-----------|-------------|-------|
| ShangRing            |           |             |       |
| Mogen clamp          |           |             |       |
| Other (specified)    |           |             |       |
| If Other, please explain: |         |             |       |
5f. ShangRing Only:

| Need for dorsal slit in the foreskin in order to insert ring, n (%) | ShangRing Group Only |
|-------------------------------------------------------------------|----------------------|
| Yes                                                               |                      |
| No                                                                |                      |

Mean length of dorsal slit (in cm)

| SD | Max | Min | Outliers |
|----|-----|-----|----------|

| Ring Size, n (%) | X   | Y   | Z   |

5g. Ring Size by Country

| Ring Size, n (%) | Uganda | Kenya | Tanzania |
|------------------|--------|-------|----------|
| X                |        |       |          |
| Y                |        |       |          |
| Z                |        |       |          |
| Step                                      | ShangRing | Mogen Clamp | Total |
|------------------------------------------|-----------|-------------|-------|
| Placement of hemostats                   | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Separation of adhesions                  | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Retraction & reduction of prepuce        | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Dorsal slit OR Placement of device (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Placement of inner ring OR Activation of the device (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Placement of outer ring (first click) OR Deactivation and removal of the device (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Skin adjustment with the ring in place OR Delivery of glans (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Locking of the outer ring (second click) OR Vaseline application (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| Excision of foreskin OR Dressing with gauze and diaper (Mogen Clamp) | No cry (0)|             |       |
|                                          | Whimper (0.5) |             |       |
|                                          | Vigorous cry (1) |   |       |
| **Total**                                |           |             |       |
| Mean (SD)                                |           |             |       |
| Min-Max                                  |           |             |       |
| Si. NIPS pain score during circumcision | ShangRing | Mogen Clamp | Total |
|----------------------------------------|-----------|-------------|-------|
| **Facial expression**                  | Relaxed   |             |       |
|                                        | Grimacing |             |       |
| **Cry**                                | No Cry    |             |       |
|                                        | Whimper   |             |       |
|                                        | Vigorous cry |         |       |
| **Breathing Pattern**                  | Relaxed   |             |       |
|                                        | Change in breathing | | |
| **Arms**                               | Restrained or Relaxed | | |
|                                        | Relaxed   |             |       |
|                                        | Flexed or Extended | | |
| **Legs**                               | Restrained or Relaxed | | |
|                                        | Relaxed   |             |       |
|                                        | Flexed or Extended | | |
| **State of arousal**                   | Sleeping or Awake | | |
|                                        | Fussy     |             |       |
| **Total NIPS score**                   |           |             |       |
| **Mean (SD)**                          |           |             |       |
| **Min-Max**                            |           |             |       |
It is important to keep in mind that dwell time was not an accurate reflection of the time it took for the anaesthetic to take effect, as the providers would check on the participants at intervals, and at times had to finish attending to other duties before coming back to check on the participant.

### 5j. Anaesthesia Information, n (%)

| Topical anaesthetic successfully used for circumcision | ShangRing | Mogen Clamp | Total |
|--------------------------------------------------------|-----------|-------------|-------|
| Yes                                                    |           |             |       |
| No                                                     |           |             |       |

If no, was there need to supplement with injectable anaesthesia after the procedure began?

Yes
No

Did the infant have a reaction to the anaesthesia

Yes
No

Was any medication given to the client before the surgical procedure was conducted?

Yes
No

### 5k. Anesthetic dwell time*

| Mean duration (in min) | ShangRing | Mogen Clamp | Total |
|------------------------|-----------|-------------|-------|
| SD                     |           |             |       |
| Max                    |           |             |       |
| Min                    |           |             |       |
| Outliers               |           |             |       |

*It is important to keep in mind that dwell time was not an accurate reflection of the time it took for the anaesthetic to take effect, as the providers would check on the participants at intervals, and at times had to finish attending to other duties before coming back to check on the participant.
5l. Were there any problems or difficulties with the circumcision procedure?

| By Site                  | ShangRing | Mogen Clamp | Total |
|--------------------------|-----------|-------------|-------|
| 1. HOMA BAY              | Yes       |             |       |
| 2. KISUMU                | Yes       |             |       |
| 3. KAKUUTO               | Yes       |             |       |
| 4. KALISIZO              | Yes       |             |       |
| 5. LYANTONDE             | Yes       |             |       |
| 6. MASAKA                | Yes       |             |       |
| 7. RAKAI                 | Yes       |             |       |
| 8. NGOME HEALTH CENTER   | Yes       |             |       |
| 9. IRINGA REGIONALHOSPITAL| Yes     |             |       |
| 10. MAFINGA DISTRICT HOSPITAL | Yes   |             |       |
| 11. ILULA HOSPITAL       | Yes       |             |       |

If yes describe

| Participant number(s) | Country | Study Arm | Description of the problem or difficulty | Frequency |
|-----------------------|---------|-----------|------------------------------------------|-----------|
|                       |         |           |                                          |           |
|                       |         |           |                                          |           |
|                       |         |           |                                          |           |
5m. The cadre of MC provider performing the MC

|                  | ShangRing | Mogen Clamp | Total |
|------------------|-----------|-------------|-------|
| Doctor           |           |             |       |
| Clinical Officer |           |             |       |
| Nurse            |           |             |       |

5n. Cadre of MC assistant

|                  | ShangRing | Mogen Clamp | Total |
|------------------|-----------|-------------|-------|
| Doctor           |           |             |       |
| Clinical Officer |           |             |       |
| Nurse            |           |             |       |
2.6 Post Operation

| 6a. NIPS pain score around 20 minutes post op, n (%) | ShangRing | Mogen Clamp | Total |
|-----------------------------------------------------|-----------|-------------|-------|
| Facial expression                                   |           |             |       |
| Relaxed                                             |           |             |       |
| Grimacing                                           |           |             |       |
| Cry                                                 |           |             |       |
| No Cry                                              |           |             |       |
| Whimper                                             |           |             |       |
| Vigorous cry                                        |           |             |       |
| Breathing Pattern                                   |           |             |       |
| Relaxed                                             |           |             |       |
| Change in breathing                                 |           |             |       |
| Arms                                                |           |             |       |
| Restrained or Relaxed                               |           |             |       |
| Relaxed                                             |           |             |       |
| Flexed or Extended                                  |           |             |       |
| Legs                                                |           |             |       |
| Restrained or Relaxed                               |           |             |       |
| Relaxed                                             |           |             |       |
| Flexed or Extended                                  |           |             |       |
| State of arousal                                    |           |             |       |
| Sleeping or Awake                                   |           |             |       |
| Fussy                                               |           |             |       |
| Total NIPS score                                    |           |             |       |
| Mean (SD)                                           |           |             |       |
| Min-Max                                             |           |             |       |

6b. Average time after operation was the pain recorded

| 6b. Average time after operation was the pain recorded | ShangRing | Mogen Clamp | Total |
|--------------------------------------------------------|-----------|-------------|-------|
| Mean                                                   |           |             |       |
| SD                                                     |           |             |       |
| Median                                                 |           |             |       |
| Min                                                    |           |             |       |
| Max                                                    |           |             |       |
### 6c. Status of the circumcision wound before discharge

| Normal | ShangRing | Mogen Clamp | Total |
|--------|-----------|-------------|-------|

If Abnormal, please describe

| Participant number(s) | Study Arm | Country | Site | Description | Frequency n |
|-----------------------|-----------|---------|------|-------------|-------------|

### 6d. Medication given during post-op period prior to discharge

| Any medication other than paracetamol given to the client to manage postoperative discomfort: Yes, n (%) |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|

If yes, state dosage

| Participant number(s) | Study Arm | Country | Site | Description |
|-----------------------|-----------|---------|------|-------------|


2.7 Follow-up

2.7.1 24hr Call Interview

| Was the phone call made successfully? | ShangRing | Mogen Clamp | Total |
|--------------------------------------|-----------|-------------|-------|
| Yes                                  |           |             |       |
| No                                   |           |             |       |

| Is the Baby well? | ShangRing | Mogen Clamp | Total |
|------------------|-----------|-------------|-------|
| Yes              |           |             |       |
| No               |           |             |       |

7b. Listing of issues reported if the baby is not well:

| Participant # | Study Arm | Country | Site | Comments |
|---------------|-----------|---------|------|----------|
|               |           |         |      |          |

2.7.2 Genital Examination

| 7c. Overall summary: Aside from the circumcision wound, are genitals normal | ShangRing | Mogen Clamp | Total |
|---------------------------------------------------------------------------|-----------|-------------|-------|
| 7-day visit                                                              |           |             |       |
| 14-day visit                                                             |           |             |       |
| 21-day visit                                                             |           |             |       |
| Participant # | Study Arm | Country | Site | Visit day | Abnormality |
|---------------|-----------|---------|------|-----------|-------------|

7d. Listing of abnormalities reported:

2.7.3 Wound Assessment (ShangRing Only)

7e. Wound Assessment
| ShangRing Group Only |
|----------------------|
| **Visit Day** | **Day 7** | **Day 14** | **Day 21** | **Day 28** | **Day 35** | **Day 42** | **Total** |
| Is the ShangRing still in place? | | | | | | | |
| Yes | | | | | | | |
| No | | | | | | | |
| Degree of separation between the ShangRing and the penis | | | | | | | |
| No detachment | | | | | | | |
| Partly detached | | | | | | | |
| Completely detached | | | | | | | |
| If detached, was the ShangRing returned to the clinic? | | | | | | | |
| Yes | | | | | | | |
| No | | | | | | | |
| Is ShangRing being removed today? | | | | | | | |
| Yes | | | | | | | |
| No | | | | | | | |
| Dressing applied after ShangRing removal | | | | | | | |
| Yes | | | | | | | |
| No | | | | | | | |
| Problems during ShangRing removal | | | | | | | |
| Yes | | | | | | | |
| No | | | | | | | |
| If yes above, explain: | | | | | | | |
### 7f. Overall summary: Reasons for ShangRing removal

| Reasons for ShangRing removal | ShangRing |
|-------------------------------|-----------|
|                               | Day 7 | Day 14 | Day 21 | Day 28 | Day 35 | Day 42 | Total |
| Pain                          |       |       |       |       |       |       |       |
| Swelling                      |       |       |       |       |       |       |       |
| Infection                     |       |       |       |       |       |       |       |
| Other (specify)               |       |       |       |       |       |       |       |

### 7g. Staff Information

| ShangRing Group Only          |       |       |       |       |       |       |       |
|-------------------------------|-------|-------|-------|-------|-------|-------|-------|
| Visit Day                     | Day 7 | Day 14 | Day 21 | Day 28 | Day 35 | Day 42 | Total |
| Number of staff assisted with the removal |
| Mean (SD)                     |       |       |       |       |       |       |       |
| Median (IQR)                  |       |       |       |       |       |       |       |
| The cadre of the person responsible for removal, n (%) |
| Physician                    |       |       |       |       |       |       |       |
| VMMC medical provider        |       |       |       |       |       |       |       |
### 7h. NIPS pain score during ring removal

|                          | ShangRing Group Only |
|--------------------------|----------------------|
|                          | Day 7 | Day 14 | Day 21 | Day 28 | Day 35 | Day 42 | Total |
| **Facial expression**    |       |        |        |        |        |        |       |
| Relaxed                  |       |        |        |        |        |        |       |
| Grimacing                |       |        |        |        |        |        |       |
| **Cry**                  |       |        |        |        |        |        |       |
| No Cry                   |       |        |        |        |        |        |       |
| Whimper                  |       |        |        |        |        |        |       |
| Vigorous cry             |       |        |        |        |        |        |       |
| **Breathing Pattern**    |       |        |        |        |        |        |       |
| Relaxed                  |       |        |        |        |        |        |       |
| Change in breathing      |       |        |        |        |        |        |       |
| **Arms**                 |       |        |        |        |        |        |       |
| Restrained or Relaxed    |       |        |        |        |        |        |       |
| Flexed or Extended       |       |        |        |        |        |        |       |
| **Legs**                 |       |        |        |        |        |        |       |
| Restrained or Relaxed    |       |        |        |        |        |        |       |
| Flexed or Extended       |       |        |        |        |        |        |       |
| **State of arousal**     |       |        |        |        |        |        |       |
| Sleeping or Awake        |       |        |        |        |        |        |       |
| Fussy                    |       |        |        |        |        |        |       |

| **Total NIPS score**     |       |        |        |        |        |        |       |
| **Mean (SD)**            |       |        |        |        |        |        |       |
| **Min-Max**              |       |        |        |        |        |        |       |

### 7i. Medication given during follow-up visit, n (%)

|                          | ShangRing | Mogen clamp | Total, n (%) |
|--------------------------|-----------|-------------|--------------|
| **Yes**                  |           |             |              |

If yes, state dosage

| Participant number(s) | Arm | Country | Site | Duration | Name of drug | Indication | Doses | Route |
|-----------------------|-----|---------|------|----------|--------------|------------|-------|-------|
### 2.7.4 Ring Removal

#### 7j. Removals Grand Totals by site

|               | ShangRing Group Only |
|---------------|-----------------------|
|               | Day 7 | Day 14 | Day 21 | Day 28 | Day 35 | Day 42 | Total |
| 1. HOMA BAY   |        |        |        |        |        |        |       |
| 2. KISUMU     |        |        |        |        |        |        |       |
| 3. KAKUUTO    |        |        |        |        |        |        |       |
| 4. KALISIZO   |        |        |        |        |        |        |       |
| 5. LYANTONDE  |        |        |        |        |        |        |       |
| 6. MASAKA     |        |        |        |        |        |        |       |
| 7. RAKAI      |        |        |        |        |        |        |       |
| 8. NGOME HEALTH CENTER | | | | | | | | |
| 9. IRINGA REGIONAL HOSPITAL | | | | | | | | |
| 10. MAFINGA DISTRICT HOSPITAL | | | | | | | | |
| 11. ILULA HOSPITAL | | | | | | | | |

**Notes on Removals in ShangRing Group**
### Participant # | Who requested (px or provider) | Reason noted & other details (i.e. he had an AE)
--- | --- | ---

#### 2.8 Healing information

| 8a. Visit day declared completely healed, n (%) | ShangRing | Mogen Clamp | Total |
|---|---|---|---|
| Day 14 |  |  |  |
| Day 21 |  |  |  |
| Day 28 |  |  |  |
| Day 35 |  |  |  |
| Day 42 |  |  |  |
| Day 49 |  |  |  |
| Unscheduled |  |  |  |
| Beyond Day 49 |  |  |  |

| 8b. Kaplan-Meier Estimates of the Cumulative Probability of Complete Healing, by Randomization Group | ShangRing | Mogen Clamp |
|---|---|---|
| Day of Study Visit | No. Left | Cum. No. Healed | Cum. Prob. Healed | 95% CI | No. Left | Cum. No. Healed | Cum. Prob. Healed | 95% CI |
| 7 |  |  |  |  |  |  |  |  |
| 14 |  |  |  |  |  |  |  |  |
| 21 |  |  |  |  |  |  |  |  |
| 28 |  |  |  |  |  |  |  |  |
8b. Kaplan-Meier Estimates of the Cumulative Probability of Complete Healing, by Randomization Group

|          | ShangRing | Mogen Clamp | Total |
|----------|-----------|-------------|-------|
| 35       |           |             |       |
| 42       |           |             |       |

1 The number of infants infants to attain complete healing and still being followed before each study visit.
2 The number of infants who attained complete healing by study visit.

8c. Time to Healing calculated in Days

|          | ShangRing | Mogen Clamp | Total |
|----------|-----------|-------------|-------|
| Mean (SD)|           |             |       |
| Median (IQR)|       |             |       |
| Min      |           |             |       |
| Max      |           |             |       |

2.9 Completion Interview

9a. Completion Interview Visit Day

|          | ShangRing | Mogen Clamp | Total |
|----------|-----------|-------------|-------|
| 7-day visit |           |             |       |
| 14-day visit |          |             |       |
| 21-day visit |          |             |       |
| 28-day visit |          |             |       |
| 35-day visit |          |             |       |
| 42-day visit |          |             |       |
9b. What was liked about the circumcision procedure (multiple responses possible)

|                                                                 | ShangRing | Mogen Clamp | Total |
|-----------------------------------------------------------------|-----------|-------------|-------|
| Less pain than expected                                        |           |             |       |
| Circumcision was quick                                          |           |             |       |
| No dressing applied to wound                                    |           |             |       |
| Improved personal hygiene                                       |           |             |       |
| Cosmetic appearance                                             |           |             |       |
| No injection needed                                             |           |             |       |
| No stitches needed                                              |           |             |       |
| The device fell off on its own                                  |           |             |       |
| Other (explain)                                                 |           |             |       |
9c. What was not liked about the circumcision procedure (multiple responses possible)  

|                                                     | ShangRing | Mogen Clamp | Total |
|-----------------------------------------------------|-----------|-------------|-------|
| More pain than expected                             |           |             |       |
| Circumcision took long to heal                       |           |             |       |
| Wound care during healing was difficult              |           |             |       |
| Not the best cosmetic appearance                    |           |             |       |
| There was nothing I disliked about the circumcision |           |             |       |
| Other (explain)                                      |           |             |       |

9d. How satisfied are you with the appearance of the healed circumcised penis? (  

| Participant’s satisfaction with the appearance of the healed circumcised penis | ShangRing | Mogen Clamp | Total |
|---------------------------------------------------------------------------------|-----------|-------------|-------|
| Very satisfied                                                                  |           |             |       |
| Somewhat satisfied                                                              |           |             |       |
| Some dissatisfied                                                               |           |             |       |
| Not satisfied at all                                                            |           |             |       |

Would you recommend circumcision at this age to another parent/LAR?  

| Yes | No |
|-----|----|
|     |    |

If no, explain why:  

|                                              |
|----------------------------------------------|
|                                              |
2.10 Adverse Events

2.10.1 Summary Data for all AEs

| 10a. Total AEs by study arm | ShangRing | Mogen Clamp | Total |
|-----------------------------|-----------|-------------|-------|
| Study arm                   |           |             |       |
| Total number of AEs         |           |             |       |
| Mild                        |           |             |       |
| Moderate                    |           |             |       |
| Severe                      |           |             |       |
| Serious                     |           |             |       |
| Total number of participants with an AE | | | |

| 10b. Total AEs by country and study arm | Uganda | Tanzania | Kenya |
|----------------------------------------|--------|----------|-------|
| Country                                | ShangRing | Mogen Clamp | ShangRing | Mogen Clamp | ShangRing | Mogen Clamp |
| Study arm                              |         |           |         |           |         |           |
| Total number of AEs                    |         |           |         |           |         |           |
| Mild                                   |         |           |         |           |         |           |
| Moderate                               |         |           |         |           |         |           |
| Severe                                 |         |           |         |           |         |           |
| Serious                                |         |           |         |           |         |           |
| Total number of participants with an AE |         |           |         |           |         |           |
### 10c. Total AEs by site and study arm

| Study arm              | ShangRing | Mogen Clamp | Total |
|------------------------|-----------|-------------|-------|
| HOMA BAY               |           |             |       |
| KISUMU                 |           |             |       |
| KAKUUTO                |           |             |       |
| KALISIZO               |           |             |       |
| LYANTONDE              |           |             |       |
| MASAKA                 |           |             |       |
| RAKAI                  |           |             |       |
| NGOME HEALTH CENTER    |           |             |       |
| IRINGA REGIONALHOSPITAL|           |             |       |
| MAFINGA DISTRICT HOSPITAL |       |             |       |
| ILULA HOSPITAL         |           |             |       |

### 10d. How related is the AE to the circumcision procedure, by study arm

| Study Arm           | ShangRing | Mogen Clamp | Total |
|---------------------|-----------|-------------|-------|
| Unrelated           |           |             |       |
| Possibly related    |           |             |       |
| Probably related    |           |             |       |
| Definitely related  |           |             |       |
### 2.10.2 Summary Data for AEs during the procedure and post-operation

10e. Total AEs during circumcision procedure & post-op period (i.e. before discharge), by study arm

| Study Arm    | ShangRing | Mogen Clamp | Total |
|--------------|-----------|-------------|-------|
| **Total number of AEs** |           |             |       |
| Mild         |           |             |       |
| Moderate     |           |             |       |
| Severe       |           |             |       |
| Serious      |           |             |       |
| **Total number of participants with an AE** |           |             |       |

10f. Total AEs during circumcision procedure & post-op period (i.e. before discharge), by country

| Country   | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
| Study Arm | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total |
| **Total number of AEs** |           |             |       |           |             |       |           |             |       |
| Mild |           |             |       |           |             |       |           |             |       |
| Moderate |           |             |       |           |             |       |           |             |       |
| Severe |           |             |       |           |             |       |           |             |       |
| Serious |           |             |       |           |             |       |           |             |       |
| **Total number of participants with an AE** |           |             |       |           |             |       |           |             |       |
### 10g. How related is the postop AE to the circumcision procedure, by study arm

| Study Arm          | ShangRing | Mogen Clamp | Total |
|--------------------|-----------|-------------|-------|
| Unrelated          |           |             |       |
| Possibly related   |           |             |       |
| Probably related   |           |             |       |
| Definitely related |           |             |       |

### 10h. How related is the postop AE to the circumcision procedure, by country and study arm

| Study Arm | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
|           | ShangRing | Mogen Clamp | Total |
|           | ShangRing | Mogen Clamp | Total |
|           | ShangRing | Mogen Clamp | Total |
| Unrelated |           |             |       |
| Possibly related |           |             |       |
| Probably related |           |             |       |
| Definitely related |           |             |       |

### 10i. Was the post-op AE treated?

|          | ShangRing | Mogen Clamp | Total |
|----------|-----------|-------------|-------|
| Yes      |           |             |       |
| No       |           |             |       |

If yes describe

| Participant ID | Study Arm | Description |
|----------------|-----------|-------------|
10j. What action was taken regarding ShangRing device

| ShangRing Group Only | None, device not present | Device not removed | Device removed |
|----------------------|--------------------------|-------------------|---------------|

10k. What action was taken regarding the ShangRing device (ShangRing Group Only) by Country

| Country   | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total |
|-----------|-----------|-------------|-------|-----------|-------------|-------|-----------|-------------|-------|
| Uganda    |           |             |       |           |             |       |           |             |       |
| Tanzania  |           |             |       |           |             |       |           |             |       |
| Kenya     |           |             |       |           |             |       |           |             |       |

10l. Postop AE resulted in death (Y/N), by country and study arm

| Study Arm | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
| Shang Ring|        |          |       |
| Mogen Clamp|       |          |       |
| Total     |        |          |       |

| Study Arm | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
| Yes       |        |          |       |
| No        |        |          |       |
Insert the AE listing here (should we just list moderate and severe?)

The listing should have these sorts of details:
Participant number #
Randomization group
Timing (intra op, post op or # days follow-up)
Type of AE
Severity (mild, moderate, severe)
Serious (yes or no)
Related (Not Related, Possibly Related, Probably Related, Definitely Related)
Action taken with ShangRing
How treated
Treatment
Medication given
Indication

Maybe it would be good to have subheading rows for each country as the country is not necessarily apparent from the participant number unless one remember what all the two letter codes are.
### 10m. AEs during the ShangRing/Mogen Clamp procedure and immediate post-operative period (before discharge)

| Study Arm                        | ShangRing | Mogen Clamp | Total |
|----------------------------------|-----------|-------------|-------|
| Total AEs                        |           |             |       |
| Type of AE                       |           |             |       |
| Excessive pain                   |           |             |       |
| Moderate                         |           |             |       |
| Severe                           |           |             |       |
| Bleeding                         |           |             |       |
| Moderate                         |           |             |       |
| Severe                           |           |             |       |
| Anaesthetic reaction             |           |             |       |
| Moderate                         |           |             |       |
| Severe                           |           |             |       |
| Severe NIPS pain                 |           |             |       |
| Moderate                         |           |             |       |
| Severe                           |           |             |       |
| Other (specify)                  |           |             |       |
| Moderate                         |           |             |       |
| Severe                           |           |             |       |
### 10n. AEs during the ShangRing/Mogen Clamp procedure and immediate post-operative period (before discharge), by country and Study Arm

| Study Arm       | Uganda | Tanzania | Kenya |
|-----------------|--------|----------|-------|
|                 | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total | ShangRing | Mogen Clamp | Total |
| Total AEs       |         |           |       |           |           |       |           |           |       |
| Type of AE      |         |           |       |           |           |       |           |           |       |
| Excessive pain  |         |           |       |           |           |       |           |           |       |
| Moderate        |         |           |       |           |           |       |           |           |       |
| Severe          |         |           |       |           |           |       |           |           |       |
| Bleeding        |         |           |       |           |           |       |           |           |       |
| Moderate        |         |           |       |           |           |       |           |           |       |
| Severe          |         |           |       |           |           |       |           |           |       |
| Anaesthetic reaction |     |           |       |           |           |       |           |           |       |
| Moderate        |         |           |       |           |           |       |           |           |       |
| Severe          |         |           |       |           |           |       |           |           |       |
| Severe NIPS pain |       |           |       |           |           |       |           |           |       |
| Moderate        |         |           |       |           |           |       |           |           |       |
| Severe          |         |           |       |           |           |       |           |           |       |
| Other (specify) |         |           |       |           |           |       |           |           |       |
| Moderate        |         |           |       |           |           |       |           |           |       |
| Severe          |         |           |       |           |           |       |           |           |       |
## 2.10.3 Summary Data for Follow-up AEs

### 10o. Total follow-up AEs, by study arm

| Study Arm       | ShangRing | Mogen Clamp | Total |
|-----------------|-----------|-------------|-------|
| Total number of AEs |           |             |       |
| Mild            |           |             |       |
| Moderate        |           |             |       |
| Severe          |           |             |       |
| Serious         |           |             |       |
| Total number of participants with an AE | | | |

### 10p. Total follow-up AEs, by country and study arm

| Country     | Uganda | Tanzania | Kenya |
|-------------|--------|----------|-------|
| Study Arm   | ShangRing | Mogen Clamp | Total |
|             | ShangRing | Mogen Clamp | Total |
|             | ShangRing | Mogen Clamp | Total |
|             | ShangRing | Mogen Clamp | Total |
| Total number of AEs | | | |
| Mild        | | | |
| Moderate    | | | |
| Severe      | | | |
| Serious     | | | |
| Total number of participants with an AE | | | |
### 10q. How related is the follow-up AE to the circumcision procedure, by study arm

| Study Arm         | ShangRing | Mogen Clamp | Total |
|-------------------|-----------|-------------|-------|
| **Unrelated**     |           |             |       |
| **Possibly related** |          |             |       |
| **Probably related** |          |             |       |
| **Definitely related** |         |             |       |

### 10r. How related is the follow-up AE to the circumcision procedure, by country and study arm

| Study Arm | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
|           | ShangRing | Mogen Clamp | Total |
| **Unrelated** |           |             |       |
| **Possibly related** |          |             |       |
| **Probably related** |          |             |       |
| **Definitely related** |         |             |       |

### 10s. Was the follow-up AE treated?

| Study Arm | ShangRing | Mogen Clamp | Total |
|-----------|-----------|-------------|-------|
| **Yes**   |           |             |       |
| **No**    |           |             |       |

If yes describe

| Participant ID | Study Arm | Description |
|----------------|-----------|-------------|
### 10t. What action was taken regarding ShangRing device

| Action                          | ShangRing Group Only |
|---------------------------------|----------------------|
| None, device not present        |                      |
| Device not removed              |                      |
| Device removed                  |                      |

### 10u. What action was taken regarding the ShangRing device (ShangRing Group Only) by Country

| Country  | Uganda | Tanzania | Kenya |
|----------|--------|----------|-------|
| None, device not present |        |          |       |
| Device not removed         |        |          |       |
| Device removed            |        |          |       |

### 10v. Follow-up AE resulted in death (Y/N), by country and study arm

| Study Arm | Uganda | Tanzania | Kenya |
|-----------|--------|----------|-------|
|           | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total |
| Yes       |        |           |       |            |              |       |            |              |       |
| No        |        |           |       |            |              |       |            |              |       |
Insert the AE listing here (should we just list moderate and severe?)

The listing should have these sorts of details:
Participant number #
Randomization group
Timing (intra op, post op or # days follow-up)
Type of AE
Severity (mild, moderate, severe)
Serious (yes or no)
Related (Not Related, Possibly Related, Probably Related, Definitely Related)
Action taken with ShangRing
How treated
Treatment
Medication given
Indication

Maybe it would be good to have subheading rows for each country as the country is not necessarily apparent from the participant number unless one remember what all the two letter codes are.
| Study Arm                  | ShangRing | Mogen Clamp | Total |
|---------------------------|-----------|-------------|-------|
| Total AEs                 |           |             |       |
| Type of AE                |           |             |       |
| Hematoma                  |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Swelling                  |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Torsion                   |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Cutaneous pinch           |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Difficulty urinating      |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Pain with erections       |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Insufficient skin removal |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Buried penis              |           |             |       |
| Moderate                  |           |             |       |
| Severe                    |           |             |       |
| Study Arm            | ShangRing | Mogen Clamp | Total |
|----------------------|-----------|-------------|-------|
| Severe NIPS pain     |           |             |       |
| Moderate             |           |             |       |
| Severe               |           |             |       |
| Other (specify)      |           |             |       |
| Moderate             |           |             |       |
| Severe               |           |             |       |
### 10x. AEs during follow up, by country

| Country | Uganda | Kenya | Tanzania |
|---------|--------|-------|----------|
| Study Arm | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total |
| Total AEs | | | | | | | | | |
| Type of AE | | | | | | | | | |
| Hematoma | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Swelling | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Torsion | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Cutaneous pinch | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Difficulty urinating | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Pain with erections | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Buried penis | | | | | | | | | |
| Moderate | | | | | | | | | |
| Severe | | | | | | | | | |
| Severe NIPS pain | | | | | | | | | |
### 10x. AEs during follow up, by country

| Country     | Uganda | Kenya | Tanzania |
|-------------|--------|-------|----------|
| Study Arm   | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total | Shang Ring | Mogen Clamp | Total |
| Moderate    |         |       |          |         |           |       |         |           |       |
| Severe      |         |       |          |         |           |       |         |           |       |
| Other (specify) |       |       |          |         |           |       |         |           |       |
| Moderate    |         |       |          |         |           |       |         |           |       |
| Severe      |         |       |          |         |           |       |         |           |       |
Annex 1: Query Response CRF

Below are the questions that were included in the form. Like the other CRFs, an electronic version was used.

1. The date this correction is being made? (read only)
   DD/MM/YYYY

2. Client ID of the eCRF in which the change is being made?

3. Type of eCRF the correction is being made?
   Demo
   Intake & Screening
   OPR
   POST-OPR
   MASTER PFU [GOTO 3a]
   IVW
   FINAL STATUS

3a. what is the visit day of the Master PFU the correction being made?
   Day 7
   Day 14
   Day 21
   Day 28
   Day 35
   Day 42
   Unscheduled

4. What is the question that is being corrected? E.g. 1, 2a, 3, 4b etc..

5. The previous value entered?

6. New value entered

7. Is there another correction that is being made on this eCRF?
   Yes [Repeat Questions 4, 5, 6 and 7 until response to question 7 = NO]
   No
### Supplementary Table. Moderate and severe adverse events based on WHO/JHPIEGO definitions.

| Adverse Event                  | Moderate                                      | Severe                                                  |
|--------------------------------|-----------------------------------------------|---------------------------------------------------------|
| **Bleeding**                   | **Tx:** pressure dressing ± skin sutures      | **Tx:** transfusion, surgical exploration, hospitalization ± transfer to another facility |
| **Infection**                  | Discharge, painful swelling/erythema, or fever | Severe infection, cellulitis, abscess                    |
| **Wound disruption**           | Defect >1.0 cm in length                      | Any defect that requires surgical repair or referral/transfer to another facility |
| **Pain**                      | NIPS score of 3-5                             | NIPS score of 5 or greater                              |
| **Penile scarring**           | Discernable but not requiring re-operation    | Discernable and requires re-operation                    |
| **Penile torsion**            | Torsion causing mild pain with erections, not requiring surgery | Painful erections requiring surgical correction         |
| **Insufficient skin removal**  | Prepuce partially covers glans when flaccid, not requiring surgery | Prepuce covers most of the glans when flaccid requiring surgical correction |
| **Excess skin removal**        | Tightness of the skin + sutures or skin mobilization needed for closure | Provider unable to close skin requiring referral to another facility |
| **Penile injury**             | Prolonged intra-operative attention or pressure dressing | **Tx:** Additional surgeries, hospitalization, transfer or transfusion |
| **Excess swelling, hematoma** | Requires only clinical intervention           | Surgical exploration required to control bleeding or removal of hematoma ± disability ≥8 days ± device placement or removal. |
| **Voiding issue**             | Requires unscheduled clinic visit but no catheter placement | **Tx:** Catheter placement, treatment referral or surgery to correct. |