NOVOTECH
The Asia Pacific CRO

STATISTICAL ANALYSIS PLAN

A randomized, data analyst-masked, 3-way cross-over, pivotal clinical investigation to evaluate the performance of two polyurethane male condoms with different size and thickness in healthy monogamous couples during vaginal intercourse compared with a commercially available thin latex male condom.

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By my signature, I confirm that this SAP has been reviewed by Reckitt and has been approved for use on the 2628301 study:

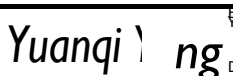
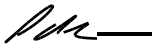
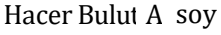
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List of Abbreviations

Abbreviation	Description
AE	*Adverse Event*
ADE	*Adverse Device Effect*
ATC	*Anatomical Therapeutic Class*
CS	*Clinically Significant*
CIR	*Clinical Investigation Report*
DBP	*Diastolic blood pressure*
ECG	*12-Lead Electrocardiogram*
eCRF	*Electronic Case Report Form*
EMSEX	*Event-Level, Male Sexual Pleasure Scale*
FAS	*Full analysis set*
GCP	*Good Clinical Practice*
GEE	*Generalised Estimating Equations*
HIV	*Human Immunodeficiency Virus*
IP	*Investigational Product*
MedDRA	*Medical Dictionary for Regulatory Activities*
N/A	*Not Applicable*
NCS	*Not Clinically Significant*
NK	*Not Known*
PT	*Preferred Term*
SAE	*Serious Adverse Event*
SAP	*Statistical Analysis Plan*
SD	*Standard Deviation*
SOC	*System Organ Class*
SOP	*Standard Operating Procedure*
WHO-DD	*World Health Organization Drug Dictionary*

1. INTRODUCTION

The following Statistical Analysis Plan (SAP) provides the outline for the statistical analysis of the data collected from the Reckitt 2628301 study (Clinical Investigation Plan (CIP) 6.0 17 Sep 2025, CRF version 7.0 dated 10 Jun 2025).
The planned analyses identified in this SAP may be included in the CIR, regulatory submissions, or future manuscripts. Also, post hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post hoc, or unplanned, exploratory analyses performed will be clearly identified as such in a post-hoc SAP as well as in final CIR. All analysis will use SAS 9.4 (or latest version that available at the time of performing the statistical analysing) for statistical programming purpose.

2. PROJECT OVERVIEW

2.1 Investigational Design

This is a randomized, data analyst-masked, 3-way cross-over pivotal clinical investigation. This investigation is designed to compare each of the performance (clinical failure rate) of two different sized Polyurethane (PU) male test condoms and the commercialized NRL male control condom based on the guidance set out in ISO 29943-1 Condoms – Guidance on clinical studies.
The clinical investigation population and investigational sites should be heterogeneous and represent males with different penis sizes therefore, this investigation will include participants recruited from 3 different geographic regions in the United States of America (USA) and the investigation population will include males with different penis sizes. Couples (one male and one female partner) will be classified into either Category 1 (which is a group of participants whose mid-shaft penis girth size is ≥ 128mm) or Penis Size Category 2 (which is a group of participants whose mid-shaft penis girth size is < 128mm) using data derived from the penis measuring tool. The lower limit of the mid-shaft measurement will be considered, the calculation used to derive the measurement is detailed in section 3.1, general consideration – penis measurement conversion.
The target proportion for each Penis Size category is approximately 150 couples, with a flexibility of ±30 couples (approximately 120 couples in one Penis Size category, with 180 couples in the other Penis Size category) however, recruitment will continue until 300 couples have been enrolled.

Three male condoms (2 test and 1 control male condom) to be evaluated are:
Test male condom 1: Polyurethane (PU) 57 ± 2 mm width, 30 ± 5 µm thickness
Test male condom 2: Polyurethane (PU) 63 ± 2 mm width, 35 ± 5 µm thickness
Control male condom: Natural Rubber Latex (NRL) (57 ± 2 mm width and 50 ± 2 µm thickness)

Following the Visit 0 consent and instruction and Visit 1 screening visits for each partner, eligible couples will attend the Visit 2 curbside visit (commencing Assessment Period 1), where they will receive their first set of a test condoms according to the randomization schedule. Within Assessment Period 1, couples will be asked to use the condoms provided for 5 separate acts of vaginal intercourse (in total 7 condoms, 2 of them are spare condoms, will be provided for each assessment

period). After each assessment period, Site staff will collect unused IP from the couple and provide them with the next condom type according to the randomization schedule, with the final collection taking place after Assessment Period 3. Participants will be informed not to use the condom if it feels too tight or too loose and causes significant pain or discomfort during use. In such cases, they will be required to contact the site for further instructions. The designated site staff will then schedule the next curbside visit to collect the unused condoms and provide the next set of test condoms according to the randomization schedule. Additional phone contacts will be conducted prior to each curbside visit as needed.

On completion of each assessment period, couples will be required to attend their next curbside visit to return their unused condoms and collect their second or third condom type (according to the randomization schedule). The exit visit will occur within 7 (+7) days after the completion of the final assessment period. The duration of the clinical investigation is anticipated to be approximately 19 weeks (from screening to follow-up).

2.2 Objectives

2.2.1 Primary objectives

- To evaluate the performance (total clinical failure) of PU male test condom (Test condom 1) compared with the NRL male control condom during vaginal intercourse in healthy monogamous couples.
- To evaluate the performance (total clinical failure) of PU male test condom (Test condom 2) compared with the NRL male control condom during vaginal intercourse in healthy monogamous couples.

2.2.2 Secondary objectives

- To evaluate the clinical breakage and clinical slippage respectively of the PU male test condom (Test condom 1) compared with the NRL male control condom when used during vaginal intercourse in healthy monogamous couples.
- To evaluate the clinical breakage and clinical slippage respectively of the PU male test condom (Test condom 2) compared with the NRL male control condom when used during vaginal intercourse in healthy monogamous couples.
- To evaluate the non-clinical breakage and non-clinical slippage respectively of each PU male test condom and the NRL male control condom when used during vaginal intercourse in healthy monogamous couples.
- To evaluate the user acceptability of the 2 PU male test condoms and the NRL male control condom

- To evaluate the in-use tolerability of the 2 PU male test condoms and the NRL male control condom

2.2.3 Safety objective

- To assess the safety of the 2 PU male test condoms and the NRL male control condom

2.2.4 Exploratory objectives

- To evaluate total clinical failure, clinical breakage, clinical slippage, non-clinical breakage, and non-clinical slippage rates in users according to whether additional lubricant was used
- To evaluate sexual pleasure during the use of 2 PU male test condoms and NRL male control condoms via EMSEX pleasure scale and Quality of Sexual Experience (QSE) Scale
- To evaluate correlations among size, fit, and performance of the 2 PU male test condoms and NRL male control condom, including factors of erect penile size (length and girth), user condom size preference (previous of and during the investigation), size of each condom type used in the investigation (PU male test and NRL male control condom), comfort/fit with condoms, and condom performance (total clinical failure, clinical breakage, clinical slippage, nonclinical breakage, and nonclinical slippage rates).

2.3 Endpoints

2.3.1 Primary endpoints

• The total clinical failure rate (combined breakage and slippage) of PU male test condom (Test condom 1) compared to the NRL male control condom

• The total clinical failure rate (combined breakage and slippage) of PU male test condom (Test condom 2) compared to the NRL male control condom

2.3.2 Secondary endpoints

- The total clinical breakage rate of the PU male test condom (Test condom 1) compared to the NRL male control condom.
- The total clinical slippage rate of the PU male test condom (Test condom 1) compared to the NRL male control condom.
- The total clinical breakage rate of the PU male test condom (Test condom 2) compared to the NRL male control condom.

- The total clinical slippage rate of the PU male test condom (Test condom 2) compared to the NRL male control condom.
- The total non-clinical breakage rate for each of the PU male test condoms and the NRL male control condom.
- The total non-clinical slippage rate for each of the PU male test condoms and the NRL male control condom.
- User acceptability, experience, and preference of each condom type will be evaluated through participant perceived questions.
- In-use tolerability of each condom type will be evaluated through participant perceived questions.

2.3.3 Safety endpoint

Overall proportion of participants with Adverse Events / Adverse Device Effects (AEs/ADEs), i.e., the occurrence of one or more AEs/ADEs per participant.

2.3.4 Exploratory endpoints

For each condom type:

- The total clinical failure rate by whether additional lubricant was used or not used.
- The total clinical breakage rate by whether additional lubricant was used or not used.
- The total clinical slippage rate by whether additional lubricant was used or not used.
- The total non-clinical breakage rate by whether additional lubricant was used or not used.
- The total non-clinical slippage rate by whether additional lubricant was used or not used.
- The total clinical failure rate (combined breakage and slippage) of PU male test condom (Test condom 2) compared to the NRL male control condom for participants in Penis Size Category 1 (mid shaft lower limit greater than or equal to 128mm).
- Score of each item, the condom pleasure subscale score, and the overall scale score in EMSEX pleasure scale from male participants for each condom type.
- Score of each item and scale score in QSE Scale from male and female participants for each condom type.
- Erectile penile length and girth measured by a given penis measuring tool.
- Evaluation through participant perceived questionnaire of users' previous experience and preference of condom size.
- Evaluation through participant perceived questionnaire of users' preference of comfort and fit of the condoms used in this investigation.

2.4 Sample Size

Data from a previously conducted study, CIP number 1003201 was used to determine the sample size used within this clinical investigation. This is a proposed 3x3 crossover

clinical investigation with two test (T_1, T_2) products and a control (C). If we first, consider this as two individual trials (i) T_1 vs C and (ii) T_2 vs C and setting the Non-Inferiority (NI) margin at 2.5% or 0.025. Then if we let each Confidence Interval (CI) be a one tailed 95% the type I error overall would be something between 5 and 10%, if we wish to control the overall type 1 error rate at ≤5% then we need to use 2 one-tailed 2.5% limits for a one-sided CI, i.e., a one-sided 97.5% CI. If the power to achieve NI for each of (i) and (ii) is set to 90% then the power to achieve both could be as small as 81% (0.90^2). Thus if we wish this to be ≥90% then each NI test should be planned for 0.95, so that $0.95^2 \approx 0.90$(90%) power (to see NI of both Tests vs C).

To retain the overall alpha level of the 3x3 we require the CI's on which the 2 NI tests are based to be 1-sided 97.5% CI's and to retain the power at 90% to achieve both T_i's to be NI to C, we need to power each test at 95%. The numbers (N's) previously calculated for a 2x2 CIP (e.g., Clearglass 1003201, one T vs C) for equal treatment group failure rates of 2%, 3% and 4% were N=86, 128 and 169 couples. Running the same calculations with the above detailed revisions on α and 1-β we obtain Total N of couples = 131, 194 and 256 for failure rates of 2%, 3% and 4% respectively. A total of 300 couples would allow a dropout rate of approximately 15% for the study to realise 256 completers, which would provide 90% power of demonstrating NI of both Tests vs Control over the range of failure rates (2-4%) foreseen in this type of investigation.

According to ISO 29943-1:2017 the investigation should enrol a sufficient number of couples, so a minimum of 200 couples complete the clinical investigation. Because of attrition, it is prudent to enrol extra participants to ensure sufficient numbers at end of clinical investigation. The clinical investigation should ensure a minimum 1000 uses of each condom type.

Considering the calculation of sample size from a previous study, the ISO guidance and potential dropouts, the aim is to enrol 300 couples across the 3 investigation locations to achieve 256 completers ensuring a minimum of 1280 uses of each condom type (which is more than 1000 uses per condom type as per the ISO guidance) for a 90% power of demonstrating NI of both Tests vs Control respectively for a 4% failure rate foreseen in this type of investigation.

2.5 Randomization

This is a data analyst-masked clinical investigation. The data analysts from the CRO and Sponsor performing and reviewing the statistical analysis will not be aware of which condom participants are randomized to use in each assessment period until the

analysis is completed and the unmasking process has been followed. The assigned unmasked statistician on this study from the vendor will generate a dummy randomisation schedule using SAS version 9.4 or higher and the assigned masked statistician from the sponsor will review the dummy schedule. After approval from the sponsor, the unmasked CRO statistician will generate the true randomisation schedule.

The CRO will hold the master randomisation schedule and will provide the master randomisation schedule to the Sponsor and Investigator for the purpose of dispensing. Upon randomisation into the clinical investigation, the participants will be assigned a unique patient randomisation number from the master randomisation schedule by an Interactive Response Technology (IRT) system. Novotech will manage the randomization of eligible study participants. Details of randomization schedule will be documented in the randomization request form(RRS).

3. STATISTICAL CONSIDERATIONS

Data will be handled and processed per the sponsor's representative (Novotech) Standard Operating Procedures (SOPs), which are written based on the principles of good clinical practice (GCP).

3.1 General Considerations

All data collected on the electronic case report form (eCRF) will be presented in the data listings, and will be sorted by study group, participant number and visit/time point. All descriptive summaries will be presented by treatment group and nominal visit/time point.

Unless otherwise stated, the following methods will be applied:

Continuous variables: summary statistics will include the number of non-missing values (n), arithmetic mean, standard deviation (SD), median, minimum and maximum values.

The minimum and maximum values will be displayed to the same decimal precision as the source data, the arithmetic mean, median values will be displayed to one more decimal than the source data for the specific variable, two more decimal for SD.

Categorical variables: summary statistics will include number (n) and percent (%) per category. The denominator in all percentage calculations will be the number of participants in the relevant analysis population with non-missing data, unless specifically stated otherwise. Percentages will be displayed to one decimal place.

Repeat/unscheduled assessments: Only values collected at scheduled study visits/within scheduled assessment periods will be presented in summary tables. If a repeat assessment was performed, the result from the original assessment will be presented as the result at the specific visit/time point. All collected data will be included in the data listings. Values collected within the time of scheduled curb side visits (defining the start and end of Assessment Periods) will be considered as scheduled observations or true observations, i.e. submitted questionnaires between curb side visit 1 and curb side visit 2 will be regarded as scheduled observations for assessment period 1, submitted questionnaires between curb side visit 2 and curb side visit 3 will be regarded as scheduled observations for assessment period 2, submitted questionnaires between curb side visit 3 and curb side visit 4 will be regarded as scheduled observations for assessment period 3. A cross examination during blinded data review of protocol deviations list and ADaM will be performed to ensure that true observations are classified into the

correct corresponding assessment period.

Assessment windows: All assessments will be included in the data listings and no visit windows will be applied to exclude assessments that were performed outside of the CIP specified procedure windows.

Result display convention: Results will be center aligned in all summary tables and listings. Participant identifiers visit and parameter labels may be left-aligned if required.

Date and time display conventions: The following display conventions will be applied in all outputs where dates and/or times are displayed:

Date only: DD-MMM-YYYY

Date and time: DD-MMM-YYYY HH:MM

If only partial information is available, unknown components of the date or time will be presented as 'NK' (not known), i.e., 'NK-NK-2016'. Times will be reported in military time.

Derivation for clinical breakage and slippage:

Answer to Condom Use Questionnaire (Version 1.0 05-Feb-2024)	**Outcome**
If Q23 = Vaginal Intercourse (only) and Q19 = Yes	Clinical Breakage
If Q23 =Vaginal Intercourse (only) and Q28 = Yes	
If Q23 = Vaginal Intercourse (only) and Q30 = Yes and Q19 = Yes	
If Q23 = Vaginal Intercourse (only) and Q30 = Yes and Q28=Yes	
If Q23 = Vaginal Intercourse (only) and Q29 = Yes and Q30=Yes	
Note: only one clinical breakage will be counted if there are more than one clinical breakage conditions reported (both Q19, Q28 and/ or Q30 =Yes in one observation.)	
If Q23 = Vaginal Intercourse (only) and Q21 = Yes	
If Q23=Vaginal Intercourse (only) and Q27= Yes and Q24 =Yes and Q25 =Yes	

Note: only one clinical slippage will be counted if there are more than one clinical slippage conditions reported (all of Q21 and Q27 and Q24 and Q25 =Yes in one observation.)	Clinical Slippage
Note: If Q32 = The condom slipped off because the condom broke or tore and Q21 or Q27 and Q24 and Q25 =Yes, do not count that as a clinical slippage event.	
Note: If a slippage is caused due to breakage then it shouldn't be counted as a separate event, the slippage and breakage should just be counted once, as a breakage event.	
Clinical Breakage or Clinical Slippage	Clinical Failure
If Q2 = Yes and reason specified by participant is condom breakage	Non-Clinical Breakage
If Q3 = Yes	
If Q7 = Yes	
If Q23 = Vaginal Intercourse (only) and Q11 = Yes and Q14 = Rolled the condom back on and went on to have intercourse even if Q19 or Q28 = Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q19 = Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q28 = Yes	
Q23 ≠ Vaginal Intercourse (only) and Q30 = Yes and Q19 = Yes	
Q23 ≠ Vaginal Intercourse (only) and Q30 = Yes and Q28=Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q29 = Yes and Q30=Yes	
If Q23 ≠ Vaginal Intercourse and Q11 = Yes AND Q14 = Rolled the condom back on and went on to have intercourse, even if Q19 or Q28 = Yes	
If Q23-Was the condom used during (corresponds to CUQ231 in condom use questionnaire raw data)	

≠ Vaginal Intercourse and Q23-Did the condom break or slip completely off the penis after intercourse during withdrawal? (corresponds to CUQ23SPCD in condom use questionnaire raw data) = Yes	
If Q29 = NO, please check the condom now = 'Yes' and Q30 = Yes but the other rules do not hold (relating to Q19 and Q28)	
If Q31 = Yes	
Q11 = Yes and Q14 = removed condom	
Q11 = Yes and Q14 did not have intercourse	
If Q23 = Vaginal Intercourse (only) AND Q27= Yes and Q24 =Yes and Q25 =No	Non- Clinical Slippage
If Q23 = Vaginal Intercourse (only) AND Q27= Yes and Q24 =No and Q25 =Yes	
If Q23 = Vaginal Intercourse (only) AND Q27= Yes and Q24 =No and Q25 =No	
If Q12 = Yes	
If Q13 = Yes	
If Q20 = Yes	
If Q26 = Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q21 = Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q27= Yes and Q24 =Yes and Q25 =Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q27= Yes and Q24 =Yes and Q25 =No	
If Q23 ≠ Vaginal Intercourse (only) and Q27= Yes and Q24 =No and Q25 =Yes	
If Q23 ≠ Vaginal Intercourse (only) and Q27= Yes and Q24 =No and Q25 =No	

Note: If a slippage is caused due to breakage then it shouldn't be counted as a separate event, the non-clinical slippage and breakage should just be counted once, as a breakage event.	

Question Codes:

Q2	Before trying to put the condom on, did you discard the condom for any reason other than condom breakage or tearing?
Q3	Before trying to put the condom on, did the condom break or tear
Q7	When putting on the condom, did the condom break or tear?
Q11	After putting on the condom but before the penis enters the vagina, did the condom break or tear? Yes/ No
Q12	After putting on the condom but before the penis enters the vagina, did the condom slip partially down the penis without coming completely off? Yes/No
Q13	After putting on the condom but before the penis enters the vagina, did the condom slip completely off the penis? Yes/No
Q14	What did you do after the slippage or breakage? Rolled the condom back on and went on to have intercourse/ Removed the condom and went on to have intercourse without a study condom/ Did not have intercourse
Q19	During intercourse, did the condom break or tear? Yes/ No
Q20	During intercourse, did the condom slip partially down the penis without coming completely off? Yes/ No
Q21	During intercourse, did the condom slip completely off the penis? Yes/ No
Q23	Was the condom used during: Vaginal intercourse/ Anal intercourse/ Oral sex If either or both of anal intercourse and oral sex is/are selected - Did the condom break or slip completely off the penis after intercourse during withdrawal?
Q24	After intercourse, was the penis still hard (erect) when it was pulled out of the vagina?

	Yes/ No
Q25	After intercourse, did you hold onto the condom ring during withdrawal from the vagina? Yes/ No
Q26	After intercourse, did the condom slip partially down the penis during withdrawal from the vagina? Yes/No
Q27	After intercourse, did the condom slip completely off the penis during withdrawal from the vagina? Yes/ No
Q28	After intercourse during withdrawal from the vagina, did the condom break or tear? Yes/ No
Q29	After the penis was withdrawn from the vagina but before the condom was removed from the penis, did you or your partner examine the used condom for breaks or tears? Yes/ No
Q30	During examination, did you find any breakage or tearing on the condom? Yes/ No
Q31	While removing the condom from the penis, did the condom break or tear? Yes/ No
Q32	(If any of Q12, Q13, Q20, Q21, Q26, Q27 answered YES) What do you think caused the condom slippage? Select all that apply The condom slipped off because the condom broke or tore/ The condom size didn't fit/ The ring of the condom didn't hold/ There was too much lubricant/ Loss of erection/ Other – please specify

Penis Measurement Conversion

- Penis measurement is collected from using the standard penis measuring tool, an example of the tool and how it looks for collecting length and girth width is below in Figure 1. There is one measurement collected for length and 3 measurements taken for penis girth, at the base of the shaft, middle of the shaft and tip of the penis. Figure 2 presents the diagram to instruct participants how to take the measurements.

Figure 1: Standard penis measuring tool

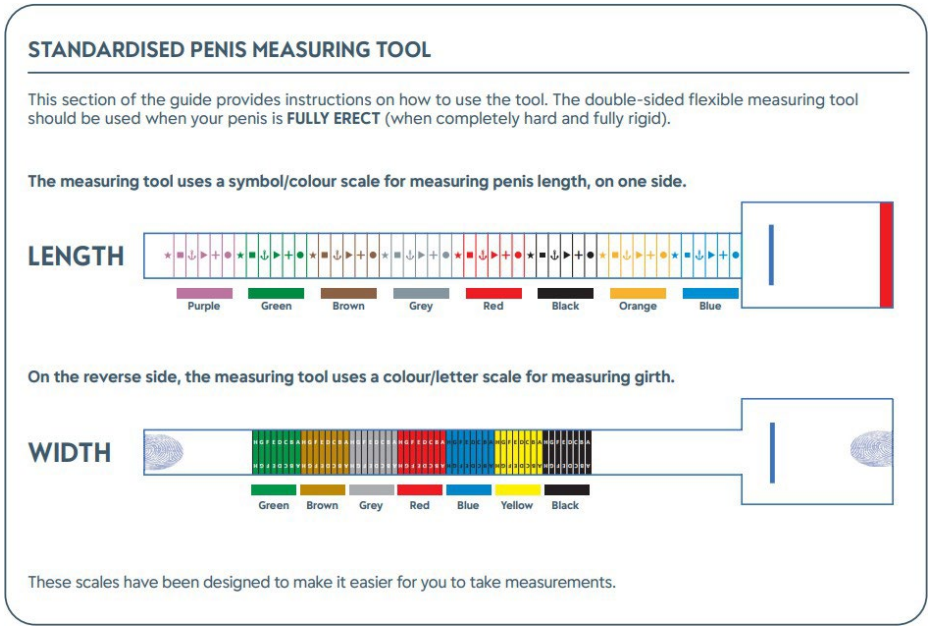
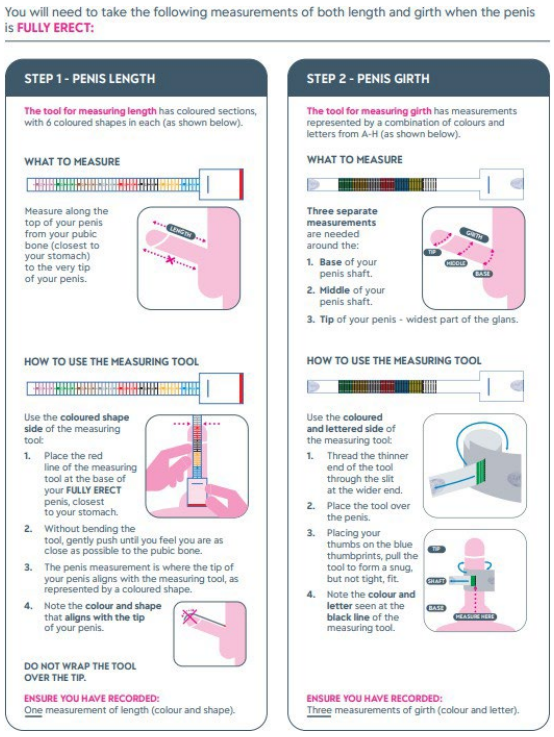


Figure 2: Instruction for using the standard penis measuring tool



To calculate the lower limit of the length of the penis measurements the following calculation is required:

- 50 + 24*(colour code-1) +(4*symbol code)-4

To calculate the upper limit of the length of the penis measurements the following calculation is required:

- 50 + 24*(colour code-1) +(4*symbol code)

To calculate the lower limit of the girth of the penis measurements the following calculation is required for each of the 3 measurements collected (base, shaft and tip):

- 59+ 16*(colour code-1)+ (2*letter code)-2

To calculate the upper limit of the girth of the penis measurements he following calculation is required for each of the 3 measurements collected (base, shaft and tip):

- 59+ 16*(colour code-1)+ (2*letter code)

3.2 Key Definitions

The following definitions will be used:

Baseline: The baseline value is defined as the last available valid (quantifiable continuous or categorical value), non-missing observation for each participant prior to randomization. Repeat and unscheduled assessments will be included in the derivation of the baseline values.

Concomitant Medications: All medications and therapies that are permitted from the date of informed consent during the course of this study should be counted as concomitant medications.

Treatment Emergent Adverse Events: An AE will be considered treatment emergent if it started since the use of the first condom. A preexisting AE which has been worsened after the use of the first condom will also be counted as a TEAE.

Treatment Emergent Adverse Device Effect: A Treatment Emergent Adverse Device Effect (TEADE) is a TEAE related (possible, probable and causal relationship) to the use of an investigational medical device.

Study day: The study day of an event is defined as the relative day of the event starting with the date of the first set of condom distribution (reference date) as Day 1).

The study day of events will be calculated as:

Study Day = (Date of Event - Date of first set of condom distribution) + 1

Study days will only be calculated for events with complete dates and will be undefined for events that are ‘Ongoing’ at the end of the study.

3.3 Handling of Missing Data

Missing Data of Date

For the classification of TEAEs and Concomitant medication, the following will be applied in the following order:

a. If all dates/times (start and stop) missing, the event/medication will automatically be classified as a TEAE/Concomitant medication.
b. For AEs with a missing start date/time, if the event end date/time is prior to first condom use, the event will not be classified as a TEAE if it does not worsen in severity after the first use of condom.
c. If only the AE start year/ medication end year is present and is the same or is after the first condom use year unit, the event/medication will be classified as a TEAE/Concomitant medication.
d. If the AE start month and year/medication end month and year are present and are the same or after the first condom use month and year units, the event/medication will be classified as a TEAE/Concomitant medication.

Missing severity and causality of AE

a. If the causality of AE is missing, the AE will be regarded as related to the treatment.
b. If any participant in the treatment group experienced same AE multiple times and all severities are missing, then the AE is assumed to be severe. If at least one but not all severities are missing, only count the most severe one.

Missing Data of Safety Endpoints

In general, missing safety endpoints or measurements will not be imputed unless otherwise specified.

Missing data of Efficacy Endpoints

Missing data of primary endpoint assessment: Any missing data (e.g., due to non-use or data errors) should be ignored in the primary analyses unless patterns are identified which suggest condom type comparisons can be biased. If such patterns are observed, efforts should be made to identify their causes and effects on analyses as per ISO 29943-1:2017 Condoms – Guidance of clinical studies.

There is a potential for data not missing at random (NMAR) due to participants of different condom size preferences testing both the PU male test condoms of different sizes and the NRL male control condom. To assess the amount and patterns of missingness, details for a data review will be documented in the data review plan. A sensitivity analysis will be performed on the data after imputation. Participants missing data for at least one of the three assessment periods will still be included in GEE analysis.

3.4 Coding of Events and Medications

Coding of AEs/ ADEs and medical history will be done using the most recent version of MedDRA V26.1 (or the most recent version if this has changed during the course of the clinical investigation) by the CRO. Concomitant medications will be coded by the CRO using the WHO dictionary (including ATC coding). All coding will be checked by the Sponsor using the most up-to-date version of MedDRA and WHO dictionary.

3.5 Treatment Groups

Assessment Period 1: starting from curb side visit 1 to curb side visit 2.
Assessment Period 2: starting from curb side visit 2 to curb side visit 3.
Assessment Period 3: starting from curb side visit 3 to curb side visit 4.
Test male condom 1: 57 ± 2 mm width, 30 µm ± 5 µm thickness
Test male condom 2: 63 ± 2 mm width, 35 µm ± 5 µm thickness
Control male condom: Natural Rubber Latex (NRL) (57 ± 2 mm width and 50 ± 2 µm thickness)
Sequence 1: T1-T2-R
Sequence 2: T1-R-T2
Sequence 3: T2-T1-R
Sequence 4: T2-R-T1
Sequence 5: R-T1-T2
Sequence 6: R-T2-T1
Participants disposition will be summarized descriptively by sequence and also by period for participant discontinuation, demographic endpoints will be summarized by sequence, and other endpoints such as safety and efficacy endpoints will be descriptively summarized by treatment group.

4. Population Descriptions

4.1 FAS (Full Analysis Set) Population

The Full Analysis Set (FAS) population will include all randomized participants who use at least one of either of the PU male test condoms or NRL male control condom. The FAS will be used for the analysis of all efficacy endpoints. For the FAS, participants will be analyzed according to their randomized treatment.

4.2 Safety Analysis Population

The safety population will include all randomised participants who use at least one of the either of the PU male test condoms or NRL male control condom. The safety population

will be used for all baseline summaries and summary of safety data. For the safety population, participants will be analysed according to treatment received.

4.3 PP (Per CIP) population

The Per CIP (PP) population will consist of all participants in the FAS who do not deviate from the CIP in such a way as to impact the evaluation of the primary endpoint. All decisions on exclusions from the PP population will be made prior to database lock. For the PP population, participants will be analysed according to treatment received. If more than 10% of the FAS population incur a CIP deviation, then the PP population will be used for sensitivity analysis of the primary endpoints.

Since this is a non-inferiority clinical investigation, both the FAS and PP populations will form the primary analysis (if a PP population is required). The FAS population will be used to confirm the primary objectives and the test of superiority.

All analysis populations will be agreed at a data review meeting prior to database lock.

5. PARTICIPANT DISPOSITION AND ANALYSIS POPULATIONS

Participant disposition and analysis population analysis will be based on all participants(randomized and non-randomized). Participant disposition and analysis populations will be summarized descriptively as described in section 3.1 (categorical descriptive analysis).

5.1 Participant Disposition

The number of participants screened will be summarized descriptively. (Table 14.1.1, listing 16.1.1,16.1.2, 16.2.1) The number of participants randomized, discontinued before treated, completing, and discontinued after treated(withdrawal), along with reasons for withdrawal, will be tabulated descriptively by sequence and period. The number of participants in each analysis population will be reported by sequence and overall.

6. PROTOCOL DEVIATIONS

Prior to database lock, all protocol deviations will be reviewed by Reckitt and will be assigned a status of Important if qualifying as such, this process is a blinded data review process and participants with protocol deviations that will impact the evaluation of the primary endpoint will be excluded from the Per Protocol population.

The protocol deviations will be summarized descriptively by PD categories and by important or non-important based on the safety population. (table 14.1.3)

All protocol deviations will be presented for each participant in the by-participant data listings.(listing 16.2.2)

A cross examination during blinded data review of protocol deviations list and ADaM will be performed to ensure that true observations are classified into the correct corresponding period.

7. DEMOGRAPHIC AND BASELINE INFORMATION

Demographic and baseline information analysis will be based on the FAS population. Demographic and baseline information will be summarized descriptively by sequence as described in section 3.1- categorical variables will be analysed as number (n) and percent (%) and continuous variables as summary statistics including n, mean, median, SD, min max (table 14.1.2, listing 16.2.3.1)

7.1 Demographics

The following demographic parameters will be analysed:

Continuous descriptive analysis:

- Age
- Penis length
- Penis girth
- Condom use preference

Categorical descriptive analysis:

- Medical history
- Injection of recreational drugs
- Biological Sex
- Childbearing potential
- Annual income/Household annual income
- Race
- Education
- Employment
- Marital status
- Penis measurement by condom use preference group
- Number of sexual partners
- Frequency of vaginal intercourse
- Times of pregnancy(Female)
- Times of being responsible for pregnancy(Male)
- Male condoms used with all partners
- Male condoms used with previous partners
- Male condoms used with current partner
- Last use a male condom with any partner
- Why use male condoms
- Like using male condoms
- Who typically suggest using a condom
- Ever refused using a condom
- Previous condom break

- Lubricant use during intercourse
- Condom brand used
- Product used
- Product used most often

In the instance where both the male and female participants in the couple have conflicting responses in the SEQ, for example Question 6 (total combined household income) and 10 (how often do you and your partner have intercourse), the male response will be summarised where appropriate and this will clearly be identified in the output, in the footnotes. There may be other instances, where there are conflicting responses, these will be discussed and agreed between Sponsor and Vendor.

7.2 Medical /Surgical history

Current and historical medical diseases, conditions or surgeries, will be collected from each partner separately and privately. All current therapies such as prescription or non-prescription drugs, including vitamins, herbal and dietary supplements, and non-pharmacological treatments such as physiotherapy from the 2 weeks prior to screening and through the end of the investigation will also be recorded. The backup method of contraception to be used during the clinical investigation will also be confirmed and recorded

Medical / Surgical history will be coded using MedDRA® and will be presented in the by-participant data listings. (listing 16.2.3.2)

7.3 Prior and Concomitant Medications

Prior and concomitant mediations will be coded up to level 4 using the World Health Organisation (WHO) dictionary (including Anatomical Therapeutic Chemical (ATC) coding- using the most recent version) All prior and concomitant medications will be presented in by-participant listings. (listing 16.2.4.1)

8 EFFICACY

Efficacy analysis for non-inferiority tests will be conducted using both FAS and PP population, PP will also be used for primary analysis if more than 10% of the population incur an important protocol deviation

Efficacy analysis for superiority tests will be conducted using FAS population.

8.1 Primary Analysis

8.1.1 The total clinical failure rate of the PU male test condom 1 compared to the NRL male control condom.

The null hypothesis and alternative hypothesis with a non-inferiority margin (δ) of 2.5%

can be written as:

H0: PU male test condom 1 total clinical failure rate – NRL male control condom total clinical failure rate ≥ 2.5%

Vs

HA: PU male test condom 1 total clinical failure rate – NRL male control condom total clinical failure rate < 2.5%

For the primary endpoint, each condom usage during vaginal intercourse will be considered either a clinical success or a clinical failure. It will be considered a clinical failure if either the condom breaks or tears during intercourse or withdrawal from the vagina, or the condom slips off completely during intercourse or during withdrawal from the vagina. Since the outcomes of each condom use by a particular couple are expected to be more alike than the outcomes of condom use by another couple, this within-couple correlation should be accounted for in the analysis. The responses for individual couple are assumed to be correlated, implying an independent working correlation structure accounting for correlation of the measurements from the same couple, which is a matrix whose diagonal is made of 1s and the rest of the matrix are all 0s:

$$\begin{bmatrix} 1 & \cdots & 0 \\ \vdots & 1 & \vdots \\ 0 & \cdots & 1 \end{bmatrix}$$

A generalised estimating equations (GEE) model with an identity link function, i.e. $g(\mu) = \mu$ and independent working correlation structure will be used to analyse the total clinical failure rate. Since for GEEs, normality is not required for neither the independent and dependent variables nor the residuals, the normality assumption does not need to be met.

Covariates will include condom type (i.e. treatment), location and investigational period. The estimated parameter estimates, corresponding 97.5% confidence interval and P-value will be obtained for condom type. (table 14.2.1.2, listing 16.2.3.4.2, 16.2.3.4.3). Interactions between condom type and centre will be investigated, and if found to be non-significant at the 10% level of significance (p>0.1), the interaction term will be dropped from the final model. The model could be expressed by:

$$g(\mu) = \beta 0 + \beta 1 * treatment_{ij} + \beta 2 * location_{ij} + \beta 3 * period_{ij} + \beta 4 * treatment_{ij} location_{ij}$$

Where i, j stands for the ith couple and jth measurement.

If an interaction is detected, then further analyses such as interaction plot(figure 14.2.1.4) will be performed to understand the nature of the interaction and the results will also be presented separately for each investigational location.

ISO 29943-1:2017 Condoms – Guidance on clinical studies for the primary endpoint requires an upper one-sided 95% confidence limit for total clinical failure rate (combined breakage and slippage) of the Polyurethane (PU) male test condoms minus Natural Rubber Latex (NRL) male control condom to be less than 2.5%. To control the overall type 1 error rate at ≤5%, non-inferiority will be concluded if the upper one-sided 97.5% confidence limit is 2.5%, if the upper one-sided 97.5% CI is equal to or above 2.5% then the investigation will have failed to demonstrate non-inferiority. If only one comparison is non-inferior, then the investigation will be considered to be a partial success.

If the upper limit is less than 2.5%, this will provide sufficient evidence that the test condom is non-inferior to the NRL control condom with respect to clinical failure.

If non-inferiority is achieved, as per ISO 29943-1:2017 Condom – Guidance on clinical studies, an upper one-sided 97.5 % confidence limit for the difference that is less than 0 % could be further interpreted as statistical evidence that the test condom is superior to the control condom. (table 14.2.1.3, listing 16.2.3.4.2, 16.2.3.4.3)

In the event of a low failure rate in the reference group, the accuracy of the GEE models deteriorates, in that the Type 1 error is inflated above 0.05. ISO 29943-1:2017 Condom – Guidance on clinical studies recommends rates of no lower than 0.5% in the reference group as the threshold. If the control group failure rate is <0.5% then an exploratory analysis will be performed at a more stringent significance level, such as an alpha level of 0.025, to help provide assurance in the investigation conclusions.

Further to the primary analysis, interactions between condom type and investigational location will be investigated, and if found to be non-significant at the 10% level of significance ($p>0.1$), the interaction term will be dropped from the final model. If the interaction term in the model is significant, then further analyses such as interaction plot(figure 14.2.1.4, listing 16.2.3.4.2, 16.2.3.4.3) will be performed to understand the nature of the interaction and the results will also be presented separately for each investigational location.

8.1.2 The total clinical failure rate of the PU male test condom 2 compared to the NRL male control condom.

The null hypothesis and alternative hypothesis with a non-inferiority margin (δ) of 2.5% can be written as:

H0: PU male test condom 2 total clinical failure rate – NRL male control condom total clinical failure rate ≥ 2.5%

Vs
HA: PU male test condom 2 total clinical failure rate – NRL male control condom total clinical failure rate < 2.5%
The same statistical analysis from section 8.1.1 will be applied. (table 14.2.1.2, listing 16.2.3.4.2, 16.2.3.4.3)

8.2 Secondary Analysis

Clinical slippage and clinical breakage rates will be analysed using the same GEE methodology with same covariates as described for the primary endpoints. Both secondary endpoints will be compared between each polyurethane test and the control NRL condom as a non-inferiority hypothesis test. In accordance with ISO 29943-1:2017 Condoms – Guidance on clinical studies, the non-inferiority margin will be slightly smaller than that specified for the total failure rate and will be set at 2.0%.

8.2.1 The total clinical breakage rate

The total clinical breakage rate of the PU male test condom 1 compared to the NRL male control condom.

The null hypothesis and alternative hypothesis with a non-inferiority margin (δ) of 2.0% can be written as:
H0: PU male test condom 1 total clinical breakage rate – NRL male condom total clinical breakage rate ≥ 2.0%
Vs
HA: PU male test condom 1 total clinical breakage rate – NRL male control condom total clinical breakage rate < 2.0%

The total clinical breakage rate of the PU male test condom 2 compared to the NRL male control condom.

H0: PU male test condom 2 total clinical breakage rate – NRL male control condom total clinical breakage rate ≥ 2.0%
Vs
HA: PU male test condom 2 total clinical breakage rate – NRL male control condom total clinical breakage rate < 2.0%

The difference in the proportion of test and reference condoms experiencing clinical breakage will be presented together with an upper one-sided 95% confidence interval. (table 14.2.2.1, table 14.2.2.2, listing 16.2.3.4.2, listing 16.2.3.4.3) If the upper limit is less than 2.0%, this will provide sufficient evidence that the test condom is non-inferior

to the reference condom with respect to clinical breakage. (table 14.2.1.3, listing 16.2.3.4.2,16.2.3.4.3)

8.2.2 The total clinical slippage rate

The total clinical slippage rate of the PU male test condom 1 compared to the NRL male control condom.

The null hypothesis and alternative hypothesis with a non-inferiority margin (δ) of 2.0% can be written as:

H0: PU male test condom 1 total clinical slippage rate – NRL male control condom total clinical slippage rate ≥ 2.0%
Vs
HA: PU male test condom 1 total clinical slippage rate – NRL male control condom total clinical slippage rate < 2.0%

The total clinical slippage rate of the PU male test condom 2 compared to the NRL male control condom.

H0: PU male test condom 2 total clinical slippage rate – NRL male control condom total clinical slippage rate ≥ 2.0%
Vs
HA: PU male test condom 2 total clinical slippage rate – NRL male control condom total clinical slippage rate < 2.0%

The difference in the proportion of test and reference condoms experiencing clinical slippage will be presented together with an upper one-sided 95% confidence interval. (table 14.2.2.3, table 14.2.2.4, 16.2.3.4.2,16.2.3.4.3) If the upper limit is less than 2.0%, this will provide sufficient evidence that the test condom is non-inferior to the reference condom with respect to clinical slippage.

For each of the above secondary endpoints, if non-inferiority is achieved, an upper one-sided 97.5 % confidence limit for the difference that is less than 0 % could be further interpreted as statistical evidence that the test condom is superior to the control condom. Clinical breakage rates, slippage rates and total clinical failure rate will be summarised as the proportion of the two polyurethane test and control NRL condoms experiencing each outcome, by treatment group, using descriptive statistics only. (table 14.2.1.1, listing 16.2.3.4.2,16.2.3.4.3)

8.2.3 The total non-clinical breakage rate of the PU male test condoms and the NRL male control condom.

Non-clinical breakage rates will be summarised as the proportion of the two polyurethane test and control NRL condoms experiencing each outcome, by treatment group, using descriptive statistics only. (table 14.2.2.5, listings 16.2.3.4.1,16.2.3.4.2,16.2.3.4.3)

8.2.4 The total non-clinical slippage rate of the PU male test condoms and the NRL male control condom.

Non-clinical slippage rates will be summarised as the proportion of the two polyurethane test and control NRL condoms experiencing each outcome, by treatment group, using descriptive statistics only. (table 14.2.2.5, listings 16.2.3.4.1,16.2.3.4.2,16.2.3.4.3)

8.2.5 User acceptability, experience and preference of each condom type, evaluated through participant perceived questionnaire and in-use tolerability of each condom type evaluated through participant perceived questionnaire

User acceptability, experience, preference, and in-use tolerability of each condom type will be summarised using descriptive statistics as described in section 3.1 for continuous endpoints and categorical endpoints separately. (table 14.2.3.9, listing 16.2.7.3)

8.3 Explanatory Analysis

8.3.1 Whether additional lubricant was used

For each of the PU male test and NRL male control condoms, the proportion experiencing total clinical failure, clinical breakage, clinical slippage, non-clinical breakage, and non-clinical slippage, will be summarised by lubricant level (before intercourse/during intercourse, Yes on the Male/ Female partner: Pea/ Dime/ Nickel/ Quarter/ More than a Quarter, No – neither partner) by descriptive statistics only. (table 14.2.3.1.1, listings 16.2.3.4.1,16.2.3.4.2,16.2.3.4.3)

8.3.2 Subgroup Analysis for participants in penis size category 1 (mid shaft lower limit greater than or equal to 128mm)

For participants in penis size category 1 (mid shaft lower limit greater than or equal to 128mm), the proportion experiencing total clinical failure will be summarized by PU male test condom (Test condom 2) and the NRL male control condom by descriptive statistics.

A fisher’s exact test will be performed to calculate the P value to evaluate the

statistical difference between the two groups. (Table 14.2.3.10, Listing 16.2.3.4.2,16.2.3.4.3).

Clinical failure rates within penis size category will be analysed using the same GEE methodology with same covariates as described for the primary endpoints. Total clinical failure rate will be compared between each polyurethane test and the control NRL condom. In accordance with ISO 29943-1:2017 Condoms – Guidance on clinical studies, the non-inferiority margin will be set at 2.5%.(Table 14.2.3.11, Listing 16.2.3.4.2,16.2.3.4.3). The purpose of this analysis is purely supplementary and non-confirmatory in nature, and the P values obtained will be unadjusted nominal P values.

8.3.3 Score of each item in EMSEX pleasure scale, the condom pleasure subscale score and the overall scale score in EMSEX pleasure scale from male participants only for each condom type

For each PU male test and NRL male control condom, the score of each item in EMSEX scale (11 items each on a 100-point sliding scale), the condom pleasure subscale score (the mean score of items 9 to 11) and the mean overall scale score in EMSEX pleasure scale (mean score of all 11 items) collected from male participants only will be summarised using summary statistics. (table 14.2.3.2, listing 16.2.7.1)

8.3.4 Score of each item and the overall scale score in Quality of Sexual Experience (QSE) Scale from both male and female participants for each condom type

For each PU male test and NRL male control condom, the score of each item in the quality of sexual experience (QSE) questionnaire (7 items, each on a 7-point scale) and the mean overall scale score of the QSE scale (mean score of all 7 items) will be collected from both male and female participants will be summarised using summary statistics only. (table 14.2.3.3, listing 16.2.7.2)

8.3.5 Additional analysis

A correlation analysis will be conducted on size, fit and performance of the 2 PU male test condoms and NRL male control condom. Penis size data will be collected by measuring the erectile penile length and girth, condom size and fit data will be collected by answering the participant perceived questionnaire of previous experience and preference of condom and the participant perceived questionnaire of user’s perception of comfort and fit of the condoms used in this investigation.

Since the correlation of the measurement from the same couple should still be considered, 5 GEE models with an identity link function and independent working

correlation structure will be used to detect any significant effect that might exist among factors of erect penile size upper limits(girth and length), user's previous condom size preference, size of different material condoms used in the investigation, comfort/ fit with condoms to condom performance.

- $P(clinical\ failure) = \beta0 + \beta1 * \text{base}_{ij} + \beta2 * \text{shaft}_{ij} + \beta3 * \text{tip}_{ij} + \beta4 * \text{length}_{ij} + \beta5 * \text{condom size preference}_{ij} + \beta6 * \text{condom type}_{ij} + \beta7 * \text{condom fit}_{ij} + \beta8 * \text{condom comfort}_{ij}$
- $P(clinical\ breakage) = \beta0 + \beta1 * \text{base}_{ij} + \beta2 * \text{shaft}_{ij} + \beta3 * \text{tip}_{ij} + \beta4 * \text{length}_{ij} + \beta5 * \text{condom size preference}_{ij} + \beta6 * \text{condom type}_{ij} + \beta7 * \text{condom fit}_{ij} + \beta8 * \text{condom comfort}_{ij}$
- $P(clinical\ slippage) = \beta0 + \beta1 * \text{base}_{ij} + \beta2 * \text{shaft}_{ij} + \beta3 * \text{tip}_{ij} + \beta4 * \text{length}_{ij} + \beta5 * \text{condom size preference}_{ij} + \beta6 * \text{condom type}_{ij} + \beta7 * \text{condom fit}_{ij} + \beta8 * \text{condom comfort}_{ij}$
- $P(nonclinical\ breakage) = \beta0 + \beta1 * \text{base}_{ij} + \beta2 * \text{shaft}_{ij} + \beta3 * \text{tip}_{ij} + \beta4 * \text{length}_{ij} + \beta5 * \text{condom size preference}_{ij} + \beta6 * \text{condom type}_{ij} + \beta7 * \text{condom fit}_{ij} + \beta8 * \text{condom comfort}_{ij}$
- $P(nonclinical\ slippage) = \beta0 + \beta1 * \text{base}_{ij} + \beta2 * \text{shaft}_{ij} + \beta3 * \text{tip}_{ij} + \beta4 * \text{length}_{ij} + \beta5 * \text{condom size preference}_{ij} + \beta6 * \text{condom type}_{ij} + \beta7 * \text{condom fit}_{ij} + \beta8 * \text{condom comfort}_{ij}$

Parameter estimates for each variable (erect penile girth , erect penile length , condom size preference +, condom size , comfort/fit) will be obtained, and according standard error, 97.5% confidence interval and P-value will also obtained from the GEE models.(table 14.2.3.4-14.2.3.8,listing 16.2.3.4.1,16.2.3.4.2,16.2.3.4.3,16.2.3.3)
Other additional analyses may be conducted on the data which will only serve as exploratory evidence and the unplanned nature of these analyses will be made clear in the Clinical investigation Report.

9 SAFETY

Safety endpoints will be analyzed using the Safety population. Safety endpoints will be summarized descriptively as described in section 3.1.

9.1 Adverse Events

All TEAEs and TEADEs including will be coded using MedDRA. Summary tables will include the number of participants (%) experiencing an event and the number of events

and will be summarized by males and females, by treatment. Participants will be counted only once for each SOC and PT level by each treatment (categorical descriptive analysis). (table 14.3.1.1-14.3.1.7, listing 16.2.5.1)

The AE summaries will include:

- Summary of TEAE.
- TEAE summary by SOC and PT.
- TEAE summary by SOC, PT and Severity.
- TEAE summary by SOC, PT and relationship to study device.
- TEADE summary by SOC and PT.
- TEADE summary by SOC, PT and Severity.

TEAE will be assigned to a treatment as described below:

If a TEAE happens in a specific period, the TEAE will be assigned to the treatment that was administered in that period.

If the participant was not being treated when the event started, the TEAE will be assigned to the last treatment group that was administered.

9.2 Pregnancy test

Pregnancy test results will be presented in by-participant listings. (listing 16.2.6.1.2)

9.3 Physical examination

Physical examination results will be presented in by-participant listings. (listing 16.2.6.1.1)

10. CHANGES TO THE PLANNED ANALYSIS

Not applicable

11. INTERIM AND FINAL ANALYSIS

11.1 Final Analysis (End of Study)

The final analysis will be conducted after all participants have completed the study, the clinical database has been locked, the analysis populations have been approved.

The final analysis will be based on the final version of the SAP. Any deviations from the planned analysis will be documented in the CIR.

12. SOFTWARE

- SAS® Version 9.4 (SAS Institute, Cary, North Carolina, USA).

13. REFERENCES

1) Clinical Study CIP Version 6.0 dated 19 Sep 2025.
2) ISO 29943-1 first edition dated July 2017.
3) 2628301-Reckitt-TS-V3.0_26Sep2025

2628301-Reckitt-SAP_V4.0_15Oct2025

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Email viewed by Simon Xu (simon.xu@novotech-cro.com)
2025-10-16 - 6:01:43 AM GMT- IP address: 52.102.12.181

Simon Xu (simon.xu@novotech-cro.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-10-16 - 6:07:29 AM GMT

Document e-signed by Simon Xu (simon.xu@novotech-cro.com)

Signing reason: I approve

Signature Date: 2025-10-16 - 6:07:34 AM GMT - Time Source: server- IP address: 223.166.128.235

Alice Switonski (alice.switonski@reckitt.com) authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

2025-10-16 - 8:30:32 AM GMT

Document e-signed by Alice Switonski (alice.switonski@reckitt.com)

Signing reason: I approve

Signature Date: 2025-10-16 - 8:30:33 AM GMT - Time Source: server- IP address: 2.222.33.59

Hacer Bulut Aksoy (hacer.bulutaksoy@reckitt.com) authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

2025-10-16 - 8:54:01 AM GMT

Document e-signed by Hacer Bulut Aksoy (hacer.bulutaksoy@reckitt.com)

Signing reason: I approve

Signature Date: 2025-10-16 - 8:54:03 AM GMT - Time Source: server- IP address: 147.161.236.95

Peter Allan (peter.allan@reckitt.com) authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

2025-10-17 - 8:00:59 AM GMT

Document e-signed by Peter Allan (peter.allan@reckitt.com)

Signing reason: I approve

Signature Date: 2025-10-17 - 8:01:02 AM GMT - Time Source: server- IP address: 165.225.197.15

Agreement completed.

2025-10-17 - 8:01:02 AM GMT