BD	**Title**: UCC-23AC023 Statistical Analysis Plan Table shells	Page No. **1 of 33**
	Study Title: UCC-23AC023 PureWick Adolescent Study **CIP/CPSP Version:** 1.0	Version No: **1.0**

Template GFM-10082B

PREPARED BY:		
Susie Xiao	30-Sept-2024	SAP Version: 1.0
(Printed Name):	Date: (DD-MMM-YYYY)	

BD	**Title**: UCC-23AC023 Statistical Analysis Plan Table shells	Page No. **2 of 33**
	Study Title: UCC-23AC023 PureWick Adolescent Study **CIP/CPSP Version:** 1.0	Version No: **1.0**

Template GFM-10082B

Table of Contents

1.0 GENERAL GUIDANCE ON OUTPUT FORMAT

It is suggested that computer-generated output adhere to the following specifications.

1.1 Document Headers and Footnotes

Unless otherwise specified, all computer-generated output should be produced in landscape mode. Required margins: at least 1.25 inches on top (the binding margin [or left for portrait output]), at least 1 inch on right, left, and bottom. All output should have the following header at top of page:

BD Page n of N CIP: UCC-23AC023 Population: Enrolled, PP, ITT, etc.

And the following as footnote:

Program name: xxxxx.sas Date DD-MMM-YYYY: hhmmss Data Source: ADSL, ADTL, ADDEV, ADIMFD, etc. Cutoff Date: DD-MMM-YYYY

1.2 Presentation of Table Numbering and Titles Within Document

Each output should be identified by a numeral followed by the title. The study population should be identified on the line immediately following the title. (example below.)

Table No. Table Title **Table Title continued (if necessary)** Study population

Other general table formatting:

- Column headings should in initial upper-case characters,
- For numeric variables, include “unit” in column heading when appropriate.
- Only these categories for which there are at least one (1) subject represented in one (1) or more groups should be included.
- Footnotes should be single spaced but separated by at least a double space from the bottom line of the table. The notes are aligned vertically by the left vertical border of the table.

1.3 Output Format

- The estimated mean, median and standard deviation (SD) for a set of values should be printed out to one more decimal place than the individual units of measurement. For example, for age, with raw data in whole years, the following precision would be used:

Example Formatting Requirements

n	xx
Mean (SD)	xx.x (xx.x)
Median	xx.x
Min – Max	xx – xx

- Percentage values should be printed with one digit to the right of the decimal point (e.g., 12.8%, 5.4%). Less-than signs “<0.1%” should be printed when values are >0.0% and <0.1% (not 0.0%).
- Missing data should be represented on subject listings as either a hyphen (“-“) with a corresponding footnote (“- = unknown or not evaluated”), or as “N/A,” or with footnote or description, whichever is appropriate.
- Dates should be printed in SAS DATE9. format (“DDMMMYYYY”: 01JUL2000). Missing portions of dates should be represented on subject listings as dashes (--JUL2000). Dates that are missing because they are not applicable for the subject are output as “N/A”, unless otherwise specified.
- Time should be printed in SAS TIME5.format (“HH:MM”: 17:30). Missing portions of time should be represented on subject listings as dashes (--:30). Times that are missing because they are not applicable for the subject are output as “N/A”, unless otherwise specified.
- Data in columns of a table should be formatted as follows:
  - Alphanumeric values are left-justified
  - Whole numbers (e.g., counts) are right-justified
  - Numbers containing fractional portions are decimal aligned
- For tables displaying counts and percent:
  - A data column entry of “n (%)” in the template indicates that the “N” in each column header will be used as denominator, unless a note indicates a different denominator is to be used.
  - A data column entry of “n/N (%)” in the template indicates that the number of non-missing data values will be used as the denominator, unless a note indicates a different denominator is to be used.

2.0 SHELLS AND SPECIFICATIONS FOR TABLES

2.1 Demographic Data Summary Figures and Tables

Table 1 Subject Disposition
Enrolled

	Number of Participants
Enrolled	n
Eligibility met	n
Randomized	N_1
Completed Study	n(%)
Discontinued prematurely	n(%)
Withdrawal of Consent	n(%)
Adverse Event	n(%)
Death	n(%)
Protocol Deviation	n(%)
Sponsor Decision	n(%)
Investigator decision	n(%)
Other	n(%)

Programming note: Display reasons of discontinuation reported for at least one subject only.
n(%) divided by N_1

Table 2 Analysis Population
Enrolled

	Total
Enrolled	n
Intent-to-Treat (ITT)	n
Per-Protocol (PP)	n

Table 3 Demographics and Baseline Characteristics by Gender
ITT

	Female (N=xxx)	Male (N=xxx)	Overall (N=xxx)
Age (Years)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min – Max	xx - xx	xx - xx	xx - xx
Ethnicity			
Hispanic or Latino	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)
Not Reported	n (%)	n (%)	n (%)
Unknown	n (%)	n (%)	n (%)
Race			

Template GFM-10082B

White	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)
American Indian or Alaska Native	n (%)	n (%)	n (%)
Asian	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)
Not Reported	n (%)	n (%)	n (%)
Unknown	n (%)	n (%)	n (%)
Two or More Races	n (%)	n (%)	n (%)
Weight (Kg)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min – Max	xx - xx	xx - xx	xx - xx
Height (cm)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min – Max	xx - xx	xx - xx	xx - xx
BMI (kg/m^2)			
N	xxx	xxx	xxx
Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
Median	xx.xx	xx.xx	xx.xx
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
BMI <40	n (%)	n (%)	n (%)
BMI >=40	n (%)	n (%)	n (%)

Table 4 Protocol Deviations

ITT

	Subject (N=xxx)
Number of Subjects with at Least One Protocol Deviation	n(%)
Total Number of Protocol Deviations	N_1
Deviation from Protocol Defined Procedure	n(%)
Clinical Assessment Not Done	n(%)
Randomization Error	n(%)
Informed Consent	n(%)
Safety Reporting	n(%)
Clinical Assessment Out of Window	n(%)
Other	n(%)
Total Number of Major Protocol Deviations	n(%)
Number of Subjects with at Least One Major Protocol Deviation	n(%)
Deviation From Protocol Defined Procedure	n(%)

Programming note: Percentage of deviations use N_1 as denominator; Percentage of Subjects use N as denominator.

2.2 Efficacy Data Summary of Figures and Tables

2.2.1 Treatment summary

Note that some questions on treatment CRF are device specific or placement specific:

Self-placed void only:

- Did the guardian/parent help the participant place the device?
- Was the device correctly connected to canister via collector tubing?
- Did HCP feel the catheter was correctly placed?
- Was catheter repositioned by participant after placement?

PureWick Flex Female only:

- Did the catheter move or become dislodged?

For percentages, the total number of non- missing data counts will be used as the denominator.

Table 5 Treatment Summary by Void
ITT

	Void 1 (N = xx)	Void 2 (N = xx)
Device Placed by		
Self Placed	n/N(%)	n/N(%)
HCP	n/N(%)	n/N(%)
Did Subject Participate in Device Placement/Void Attempt		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Any Signs of Injury or Irritation in The Perineal Region Prior to Device Placement		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was Device Placed		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Device		
PureWick Flex Female	n/N(%)	n/N(%)
PureWick Male	n/N(%)	n/N(%)
Did the Guardian/Parent Help the Participant Place the Device		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was the Device Correctly Connected to Canister via Collector Tubing		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did HCP feel the catheter was correctly placed		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)

Was Catheter Repositioned by Participant After Placement		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the Participant Have a Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the catheter move or become dislodged		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was There Any Leakage Observed by HCP After the Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Are There Any Signs of Injury or Irritation in the Perineal Region or Adverse Reactions After Device Removal		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Pad Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Pad Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Canister Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Caniser Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx

Table 6 Treatment Summary by Placement

ITT

	Self Placed (N = xx)	HCP (N = xx)
Void		
1	n/N(%)	n/N(%)
2	n/N(%)	n/N(%)
Did Subject Participate in Device Placement/Void Attempt		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Any Signs of Injury or Irritation in The Perineal Region Prior to Device Placement		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was Device Placed		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Device		
PureWick Flex Female	n/N(%)	n/N(%)
PureWick Male	n/N(%)	n/N(%)
Did the Guardian/Parent Help the Participant Place the Device		
Yes	n/N(%)	N/A
No	n/N(%)	N/A
Was the Device Correctly Connected to Canister via Collector Tubing		
Yes	n/N(%)	N/A
No	n/N(%)	N/A
Did HCP feel the catheter was correctly placed		
Yes	n/N(%)	N/A
No	n/N(%)	N/A

Was Catheter Repositioned by Participant After Placement		
Yes	n/N(%)	N/A
No	n/N(%)	N/A
Did the Participant Have a Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the catheter move or become dislodged		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was There Any Leakage Observed by HCP After the Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Are There Any Signs of Injury or Irritation in the Perineal Region or Adverse Reactions After Device Removal		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Pad Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Pad Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Canister Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Caniser Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx

Table 7 Treatment Summary by Device

ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Void		
1	n/N(%)	n/N(%)
2	n/N(%)	n/N(%)
Device Placed by		
Self Placed	n/N(%)	n/N(%)
HCP	n/N(%)	n/N(%)
Did Subject Participate in Device Placement/Void Attempt		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Any Signs of Injury or Irritation in The Perineal Region Prior to Device Placement		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was Device Placed		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the Guardian/Parent Help the Participant Place the Device		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Was the Device Correctly Connected to Canister via Collector Tubing		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did HCP feel the catheter was correctly placed		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)

Was Catheter Repositioned by Participant After Placement		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the Participant Have a Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Did the catheter move or become dislodged		
Yes	n/N(%)	N/A
No	n/N(%)	N/A
Was There Any Leakage Observed by HCP After the Void		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Are There Any Signs of Injury or Irritation in the Perineal Region or Adverse Reactions After Device Removal		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)
Pad Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Pad Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Canister Starting Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Caniser Final Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx

2.2.2 Primary Endpoint 1 - Capture Rate

Weight of Captured Urine = $Canister\ final\ weight - Canister\ starting\ weight$

Weight of Urine Leak = $Bed\ pad\ final\ weight - Bed\ pad\ starting\ weight$

Void Weight = $Weight\ of\ Captured\ Urine + Weight\ of\ Urine\ Leak$

Capture Rate = $\frac{weight\ of\ captured\ urine \times 100\%}{weight\ of\ captured\ urine + weight\ of\ urine\ leak}$

Voids with weight (captured + leak) >= 10 g is considered evaluable.

Capture rate is calculated from evaluable voids only.

Table 8a Void Summary by Device
ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Captured Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Leaked Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Void Weight (g)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx
Evaluable Void	n (%)	n (%)

Table 8b Capture Rate by Device
ITT

Capture Rate (Evaluable Voids Only)	PureWick Flex Female Evaluable (N_1 = xx)	PureWick Male Evaluable (N_1 = xx)
Mean (SD)	xx.x% (xx.x%)	xx.x% (xx.x%)
Median	xx.x%	xx.x%
Min - Max	xx.x%	xx.x%

Note: Voids with weight (captured + leak) >= 10 g is considered evaluable.

Table 9a Void Summary by Device and Placement

ITT

	HCP			SelfPlaced		
Device	PureWick Flex Female (N = xx)	PureWick Male (N = xx)	HCP Overall (N = xx)	PureWick Flex Female (N = xx)	PureWick Male (N = xx)	SelfPlaced Overall (N = xx)
Captured Weight (g)						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx
Leaked Weight (g)						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx
Void Weight (g)						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx	xxx-xxx
Evaluable Void	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Table 9b Capture Rate by Device and Placement

ITT

	HCP			SelfPlaced		
Capture Rate (Evaluable Voids Only)	PureWick Flex Female Evaluable (N_1 = xx)	PureWick Male Evaluable (N_1 = xx)	HCP Overall Evaluable (N_1 = xx)	PureWick Flex Female Evaluable (N_1 = xx)	PureWick Male Evaluable (N_1 = xx)	SelfPlaced Overall Evaluable (N_1 = xx)
Mean (SD)	xx.x% (xx.x%)	xx.x% (xx.x%)	xx.x% (xx.x%)	xx.x% (xx.x%)	xx.x% (xx.x%)	xx.x% (xx.x%)
Median	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Min - Max	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

Note: Voids with weight (captured + leak) >= 10 g is considered evaluable.

2.2.3 Primary Endpoint 2 - Perception of Wetness

Table 10 Perception of Wetness Summary by Device

ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Void Type		
After HCP Placement Void	n (%)	n (%)
After Self Placement Void	n (%)	n (%)
Questionnaire Completed		
Yes	n (%)	n (%)
No	n (%)	n (%)
How Wet or Dry did You Feel after Your Urination		
1- Extremely Wet	n/N(%)	n/N(%)
2- Very Wet	n/N(%)	n/N(%)
3- Somewhat Wet	n/N(%)	n/N(%)
4- Slightly Wet but Acceptably Dry	n/N(%)	n/N(%)
5- Dry	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
Did You Feel Leakage While Voiding During Use of the Device		
Yes	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)

Table 11 Perception of Wetness Summary by Device and Placement

ITT

	After HCP Placement Void			After Self Placement Void		
	PureWick Flex Female (N = xx)	PureWick Male (N = xx)	After HCP Overall (N = xx)	PureWick Flex Female (N = xx)	PureWick Male (N = xx)	After Self Overall (N = xx)
Questionnaire Completed						
Yes	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
How Wet or Dry did You Feel after Your Urination						
1- Extremely Wet	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)
2- Very Wet	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)
3- Somewhat Wet	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)
4- Slightly Wet but	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)

Acceptably Dry						
5- Dry	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min-Max	xx-xx	xx-xx	xx-xx	xx-xx	xx-xx	xx-xx
Did You Feel Leakage While Voiding During Use of the Device						
Yes	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)
No	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)	n/N(%)

2.2.4 Secondary Endpoint 1 – Ease of Use Score

Table 12 Participant Ease of Use Questionnaire, Common Questions for Both Devices
ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Questionnaire Completed		
Yes	n (%)	n (%)
No	n (%)	n (%)
How Easy was the Placement of the Device?		
1-Very Difficult	n/N(%)	n/N(%)
2-Somewhat Difficult	n/N(%)	n/N(%)
3-Average Difficulty	n/N(%)	n/N(%)
4-Somewhat Easy	n/N(%)	n/N(%)
5-Very Easy	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
How Easy was the Removal of the Device?		
1-Very Difficult	n/N(%)	n/N(%)
2-Somewhat Difficult	n/N(%)	n/N(%)
3-Average Difficulty	n/N(%)	n/N(%)
4-Somewhat Easy	n/N(%)	n/N(%)
5-Very Easy	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx

Table 13 Participant Ease of Use Questionnaire, PureWick Flex Only Questions
ITT Female

	PureWick Flex Female (N = xx)
I was Able to Connect the Device PureWick Flex FEC Tubing	
1-Strongly Disagree	n/N(%)
2-Disagree	n/N(%)
3-Neutral	n/N(%)
4-Agree	n/N(%)
5- Strongly Agree	n/N(%)
Mean(SD)	xx.x (xx.x)
Median	xx.x
Min-Max	xx-xx
I was Able to Locate the Vent Hole on the PureWick Flex FEC	
1-Strongly Disagree	n/N(%)
2-Disagree	n/N(%)
3-Neutral	n/N(%)
4-Agree	n/N(%)
5- Strongly Agree	n/N(%)
Mean(SD)	xx.x (xx.x)
Median	xx.x
Min-Max	xx-xx
I would be able to tell if the PureWick Flex FEC came out of place	
1-Strongly Disagree	n/N(%)
2-Disagree	n/N(%)
3-Neutral	n/N(%)
4-Agree	n/N(%)
5- Strongly Agree	n/N(%)
Mean(SD)	xx.x (xx.x)
Median	xx.x
Min-Max	xx-xx
I would be able to tell if the PureWick Flex FEC was in the Correct Orientation	
1-Strongly Disagree	n/N(%)
2-Disagree	n/N(%)
3-Neutral	n/N(%)
4-Agree	n/N(%)

5- Strongly Agree	n/N(%)
Mean(SD)	xx.x (xx.x)
Median	xx.x
Min-Max	xx-xx
I Would be Able to Curve the PureWick Flex FEC to Fit My Body	
1-Strongly Disagree	n/N(%)
2-Disagree	n/N(%)
3-Neutral	n/N(%)
4-Agree	n/N(%)
5- Strongly Agree	n/N(%)
Mean(SD)	xx.x (xx.x)
Median	xx.x
Min-Max	xx-xx

Table 14 HCP Ease of Use Questionnaire

HCP

	PureWick Flex Female (HCP N = xx)	PureWick Male (HCP N = xx)
Questionnaire Completed		
Yes	n (%)	n (%)
No	n (%)	n (%)
How Easy was the Placement of the Device?		
1-Very Difficult	n/N(%)	n/N(%)
2-Somewhat Difficult	n/N(%)	n/N(%)
3-Average Difficulty	n/N(%)	n/N(%)
4-Somewhat Easy	n/N(%)	n/N(%)
5-Very Easy	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
How Easy was the Removal of the Device?		
1-Very Difficult	n/N(%)	n/N(%)
2-Somewhat Difficult	n/N(%)	n/N(%)
3-Average Difficulty	n/N(%)	n/N(%)
4-Somewhat Easy	n/N(%)	n/N(%)
5-Very Easy	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx

2.2.5 Secondary Endpoint 2 – Overall Comfort Score

Table 15 Participant Comfort Scale Survey
ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Questionnaire Completed		
Yes	n (%)	n (%)
No	n (%)	n (%)
How Comfortable was the Placement?		
1-Very Uncomfortable	n/N(%)	n/N(%)
2-Uncomfortable	n/N(%)	n/N(%)
3-Neither Comfortable Nor Uncomfortable	n/N(%)	n/N(%)
4-Comfortable	n/N(%)	n/N(%)
5-Very Comfortable	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
How Comfortable was the Device While Voiding?		
1-Very uncomfortable	n/N(%)	n/N(%)
2-Uncomfortable	n/N(%)	n/N(%)
3-Neither Comfortable Nor Uncomfortable	n/N(%)	n/N(%)
4-Comfortable	n/N(%)	n/N(%)
5-Very Comfortable	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
How Comfortable was the Removal of the External Catheter?		
1-Very uncomfortable	n/N(%)	n/N(%)
2-Uncomfortable	n/N(%)	n/N(%)
3-Neither Comfortable Nor Uncomfortable	n/N(%)	n/N(%)
4-Comfortable	n/N(%)	n/N(%)
5-Very Comfortable	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
How Likely Would You Recommend the External Catheter to Someone Else?		
1-Very Unlikely	n/N(%)	n/N(%)
2-Unlikely	n/N(%)	n/N(%)
3-Neither likely Nor Unlikely	n/N(%)	n/N(%)
4-Likely	n/N(%)	n/N(%)
5-Very Likely	n/N(%)	n/N(%)

Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx

2.2.6 Secondary Endpoint 3 - IFU comprehension score

Table 16 Participant IFU Comprehension Survey
ITT

	PureWick Flex Female (N = xx)	PureWick Male (N = xx)
Questionnaire Completed		
Yes	n (%)	n (%)
No	n (%)	n (%)
I Was Able to Understand and Follow the Written Instructions		
1-Strongly Disagree	n/N(%)	n/N(%)
2-Disagree	n/N(%)	n/N(%)
3-Neutral	n/N(%)	n/N(%)
4-Agree	n/N(%)	n/N(%)
5- Strongly Agree	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
I Was Able to Understand the Pictures in the Instructions		
1-Strongly Disagree	n/N(%)	n/N(%)
2-Disagree	n/N(%)	n/N(%)
3-Neutral	n/N(%)	n/N(%)
4-Agree	n/N(%)	n/N(%)
5- Strongly Agree	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx
I Was Able to Place the PureWick External Catheter on Myself		
1-Strongly Disagree	n/N(%)	n/N(%)
2-Disagree	n/N(%)	n/N(%)
3-Neutral	n/N(%)	n/N(%)
4-Agree	n/N(%)	n/N(%)
5- Strongly Agree	n/N(%)	n/N(%)
Mean(SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min-Max	xx-xx	xx-xx

2.3 Safety Data Summary of Figures and Tables

Adverse events will be listed.

3.0 SHELLS AND SPECIFICATIONS FOR LISTINGS

3.1 Subject Data Listings

3.1.1 Screen Failure

Listing 1 Screen Failures
Enrolled

Subject ID	Eligibility criteria not met

3.1.2 Enrollment details

Listing 2 Randomization and Treatment Status
Enrolled

Subject ID	Eligibility Met	Randomized?	Date of Randomization	Randomization No.	Randomized Sequence
		Yes			
		No			

Listing 3 End of Study Status
ITT

Subject ID	Date of Study Completion/Discontinuation	Status	Other, Specify	Date of death	Primary cause of death

Listing 4 Protocol Deviations

ITT

Subject ID	Date of Deviation	Nature of Deviation	Additional Details	Major Protocol Deviation

3.1.4 Patients excluded from the Efficacy Analysis

Listing 5 Voids did not meet Evaluable Criteria

ITT

Subject ID	Void	Device Placed By	Device	Did the Participant Have a Void	Pad Starting Weight (g)	Pad Final Weight (g)	Canister Starting Weight (g)	Canister Final Weight (g)

3.1.5 Demographics Data

Listing 6 Demographic Data
ITT

Subject ID	Informed Consent Date	Age	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
	10MAR2024				Not Hispanic Or Latino	170.0	109.0	37.7

3.1.6 Individual Efficacy Response data

Listing 7 Treatment Details (Part 1)
ITT

Subject ID	Void	Was Device Placed	Device Placed by	Device	Did Participant Have a Void	Signs of Irritation Prior (If yes, specify)	Signs of Irritation After (If yes, specify)	Did the Catheter Move/Dislodged	Any Leakage Observed by HCP
	Void 1	Yes	HCP						
	Void 2	Yes	SelfPlaced						

Listing 8 Treatment Details (Part 2)
ITT

Subject ID	Void	Was Device Placed	Device Placed by	Device	Did Subject Participate in Device Placement/Void Attempt	Did the Guardian/Parent Help the Participant Place the Device	Was the Device Correctly Connected to Canister via Collector Tubing (If No, Reason; If Other, Specify)	Did HCP Feel the Catheter was Correctly Placed	Was Catheter Repositioned by Participant After Placement
	Void 1	Yes	HCP						
	Void 2	Yes	SelfPlaced						

Listing 9 Treatment Details (Part 3)
ITT

Subject ID	Void	Was Device Placed	Device Placed by	Device	Pad Starting Weight (g)	Pad Final Weight (g)	Canister Starting Weight (g)	Canister Final Weight (g)
	Void 1							
	Void 2							

Listing 10 Capture Rate
ITT

Subject ID	Void	Device Placed by	Device	Leaked Weight (g)	Captured Weight (g)	Void Weight (g)	Evaluable	Capture Rate (%)
	Void 1						Yes	
	Void 2						No	N/A, Not Evaluable

Listing 11 Participant - Perception of Wetness

ITT

Subject ID	Void	Device	Void Type	Questionnaire Completed	How Wet or Dry did You Feel After Your Urination	Comments if selected 1/2/3	Did you Feel Leakage While Voiding
	Void 1				1-Extremely Wet		Yes
	Void 2						

Listing 12 Participant Ease of Use – Both Device

ITT

Subject ID	Questionnaire Completed	Device	How Easy was the Placement of the Device	How Easy was the Removal of the Device
		PureWick Flex Female	1-Very Difficult	
		PureWick Male		

Listing 13 Participant Ease of Use – PureWick Flex Female only
ITT

Subject ID	Able to Connect the Device Tubing (If 1/2/3, comments)	Able to Locate the Vent Hole (If 1/2/3, comments)	Able to Tell if Came Out of Place (If 1/2/3, comments)	Able to Tell if in Correct Orientation (If 1/2/3, comments)	Able to Curve to Fit (If 1/2/3, comments)
	1- Strongly Disagree (xxxxx)				

Listing 14 HCP Ease of Use
ITT

HCP Initials	Questionnaire Completed	Device	How Easy was the Placement of the Device	How Easy was the Removal of the Device
		PureWick Flex Female	1-Very Difficult	5-Very Easy
		PureWick Male		

Listing 15 Participant IFU
ITT

Subject ID	Questionnaire Completed	Device	Able to Understand Written Instructions (If 1/2/3, comments)	Able to Understand Pictures Instructions (If 1/2/3, comments)	Able to Place on Myself (If 1/2/3, comments)
		PureWick Flex Female	1-Strongly Disagree (xxxxxx)		
		PureWick Male			

Listing 16 Participant Comfort Scale Survey
ITT

Subject ID	Questionnaire Completed	Device	How Comfortable was the Placement	How Comfortable was the device while voiding	How Comfortable was the Removal	How Likely to Recommend
			2-Uncomfortable	1-Very Uncomfortable	5-Very Comfortable	4-Likely

Listing 17 Adverse Events

ITT

Subject ID	AE(Reported)/SOC/PT	Start Date / End Date	Outcome of AE	Severity	Relation to Study Device	Relation to Procedure	SAE	UADE	Additional Details
					Yes/xxx	Yes/xxx		Yes/No	
					No				

Listing 18 Serious Adverse Events

ITT

Subject ID	AE(Reported)/SOC/PT	Start Date	Result in Death	Life Threatening or Injury	If Require or Prolongs Hospitalization		Permanent Impairment of a Body Structure or Function	Necessitates Medical or Surgical Intervention	Fetal Distress, Fetal Death, Congenital Anomaly or Birth Defect	Meet Definition of Serious Health Threat
					Admission Date	Discharge Date				

3.1.9 Device Deficiency

Listing 19 Device Deficiencies
ITT

Subject ID	Date of Device Deficiencies	Time of Device Deficiencies	Device Name/identifier	Failure Code	Details	Additional Details	Lot Number	Device Used to Treat Subject	AE Associated with Device Deficiencies	Could the Device Deficiency Meet SADE	Meet Definition of Serious Health Threat
	DDMMYYYY							Yes/No	Yes/No		

4.0 REFERENCES

N/A

5.0 VERSION HISTORY

Vers. #	Date	Change Owner	Description of Change(s)
1.0	9/30/2024		Original

Signature Page for VV-TMF-319540 v1.0

Reason for signing: Finalize	Name: Ajesh Raju Role: Clinical Project Management Date of signature: 30-Sep-2024 20:06:09 GMT+0000

Reason for signing: Finalize	Name: Swathi Vasireddi Role: Clinical Statistical Programmer Date of signature: 30-Sep-2024 20:44:55 GMT+0000

Reason for signing: Finalize	Name: Yanchang Zhang Role: Clinical Statistician Date of signature: 01-Oct-2024 16:10:09 GMT+0000

Reason for signing: Finalize	Name: Danielle Redmond Role: Medical Affairs Core Team Member Date of signature: 02-Oct-2024 14:19:49 GMT+0000

Reason for signing: Finalize	Name: Shujie (Susie) Xiao Role: Clinical Statistician Date of signature: 02-Oct-2024 20:43:35 GMT+0000

Signature Page for VV-TMF-319540 v1.0