

CLINICAL INVESTIGATION PLAN

Title: A Comparative Crossover Study on the Safety, Efficacy, and Patient Reported Satisfaction of the PureWick™ System with an Established Comparator Overnight in the Home Setting for Incontinence in Adult Males

Protocol No.: UCC-24HC013

NCT No.: NCT06850259

Sponsor: Becton, Dickinson and Company
8195 Industrial Blvd.
Covington, GA 30014

Version & Date: Version 1.0 – December 18, 2024

	Title: Clinical Investigation Plan	
	Study ID: UCC-24HC013	Version No: 1.0

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Clinical Investigation Plan	
Study Title	A Comparative Crossover Study on the Safety, Efficacy, and Patient Reported Satisfaction of the PureWick™ System with an Established Comparator Overnight in the Home Setting for Incontinence in Adult Males (Short title: PUREST-M pilot)
Study ID	UCC-24HC013
CIP Version and Date	V1.0 18-DEC-2024
Registration Number(s)	ClinicalTrials.gov
Study Device	PureWick™ Male External Catheter (PWMX30) PureWick™ Urine Collection System (PW100, PW200) UltraFlex™ Self-Adhering Male External Catheter
Sponsor Name	Becton, Dickinson and Company 8195 Industrial Blvd. Covington, GA 30014
Sponsor Contact	Ajesh Raju Clinical Project Manager Ajesh.raju@bd.com
Coordinating Investigator	Adrian Wagg, MB, BS, FRCP, FHES, FCGS (MD) 1-198 Clinical Sciences Building 11350 83 Avenue Edmonton, Alberta T6G 2PF
Participating Clinical Sites	A list of participating clinical sites, Principal Investigators, and the relevant contact information is maintained in the Trial Master File (TMF).
Funding	This study is funded by Becton, Dickinson and Company as sponsor of the study. A clinical study agreement will be executed between the sponsor and participating clinical sites, which details obligations and responsibilities related to the study conduct, as well as the financial arrangements to reimburse for the efforts at the clinical site.
Confidentiality Statement: This document contains information that is the confidential and proprietary property of Becton, Dickinson and Company (BD) or its affiliates. Neither this document nor the information therein may be reproduced, used, or disclosed to or for the benefit of any third party without the prior consent of BD. Investigators are cautioned that the information given in this document might be subject to change and revision.	

	Title: Clinical Investigation Plan	
	Study ID: UCC-24HC013	Version No: 1.0

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CLINICAL INVESTIGATION PLAN SIGNATURE PAGE

1. I have read the Clinical Investigation Plan including all appendices and agree to conduct this study as outlined herein.
2. I agree to comply with ISO 14155, 21 CFR 812, ethical principles with their origin in the Declaration of Helsinki.
3. I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation conduct of the study without the prior written consent of Becton Dickinson (BD).
4. I attest that I have signed the applicable clinical study agreement as a party or as having 'read and acknowledged' such agreement, and, by signing below, confirm that I accept the terms of such agreement as they relate to my activities and obligations as the study Principal Investigator and that such activities and obligations will not conflict with any contractual obligations I may have to my employer or others.

Investigator Signature		
Printed Name	Signature	Date (DD/MMM/YYYY):
Clinical Site Name		

	Title: Clinical Investigation Plan	
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Table of Contents

1.0 SYNOPSIS.....	1
2.0 ABBREVIATIONS	3
3.0 STUDY SCHEDULE	5
3.1 Study Schema.....	5
3.2 Schedule of Activities	5
4.0 INTRODUCTION	6
4.1 Background	6
4.2 Rationale.....	7
5.0 IDENTIFICATION AND DESCRIPTION OF THE STUDY DEVICE	7
5.1 Study Device(s)	7
5.2 Equipment to be Used in Study.....	9
6.0 OBJECTIVES AND HYPOTHESES.....	9
6.1 Objectives and Endpoints.....	9
6.2 Performance Goal.....	10
7.0 DESIGN OF THE STUDY.....	10
7.1 Study Design and Justification.....	10
7.2 Treatment Allocation and Measures to Minimize Bias.....	11
7.3 Potential Influencing or Confounding Factors and Bias	11
7.4 End of Study Definition	11
8.0 BENEFITS AND RISKS OF THE STUDY DEVICE, CLINICAL PROCEDURE(S), AND THE STUDY	11
8.1 Benefit Assessment	12
8.2 Risk Assessment.....	12
8.3 Risk / Benefit Analysis.....	14
9.0 SUBJECTS	14
9.1 Inclusion Criteria.....	14
9.2 Exclusion Criteria.....	14
9.3 Vulnerable Subjects.....	15
9.4 Point of Enrollment	15
9.5 Screen Failures and Replacement of Subjects.....	15

	Title: Clinical Investigation Plan	
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

9.6	Study / Participation Duration.....	15
9.7	Subject Discontinuation / Withdrawal [and Discontinuation of Intervention]	16
9.8	Subject Compensation.....	16
10.0	PROCEDURES.....	16
10.1	Screening Procedures	17
10.2	Medical History / Baseline Assessments.....	17
10.3	Enrollment	17
10.4	Randomization.....	17
10.5	Home Care Nurse Introduction.....	17
10.6	Efficacy Assessment(s) – Urine Capture.....	18
10.7	Baseline	19
10.8	Device Use Nights 1-7 (Treatment 1 & Treatment 2)	20
10.9	Wash-out Period	21
10.10	End of Treatment	21
11.0	STATISTICAL METHODS.....	21
11.1	Sample Size Considerations	21
11.2	Analysis Population.....	21
11.3	General Considerations.....	21
11.4	Final Analysis	22
11.5	Interim Analysis	23
12.0	DATA MANAGEMENT.....	23
12.1	Case Report Forms	23
12.2	Source Documentation	23
12.3	Record Retention	23
13.0	MONITORING PLAN	24
14.0	AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN	24
15.0	DEVIATIONS FROM THE CLINICAL INVESTIGATION PLAN	24
16.0	DEVICE ACCOUNTABILITY.....	25
17.0	STATEMENT OF COMPLIANCE.....	25
18.0	INFORMED CONSENT PROCESS AND OTHER ETHICAL/REGULATORY CONSIDERATIONS.....	26
18.1	Informed Consent	26

	Title: Clinical Investigation Plan	
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

18.2	IRB/EC Approval	26
18.3	Confidentiality	27
19.0	ADVERSE EVENTS, ADVERSE DEVICE EFFECTS, AND DEVICE DEFICIENCIES	27
19.1	Definitions of Events	27
19.2	Severity of Adverse Events	29
19.3	Relationship of Adverse Event to Device(s)/Procedure	29
19.4	Reporting of Events	31
19.5	Safety Committees.....	32
20.0	SUSPENSION OR PREMATURE TERMINATION OF THE STUDY.....	32
21.0	PUBLICATION POLICY	33
22.0	STUDY REGISTRATION	33
23.0	ADMINISTRATIVE REQUIREMENTS	33
23.1	Audits and Inspections.....	33
23.2	Investigator and Clinical Site Selection.....	33
23.3	Training	34
23.4	Required Documents	34
23.5	Regulatory Status.....	34
24.0	REFERENCES	35
25.0	VERSION HISTORY	35
26.0	APPENDICES	36
26.1	Appendix 1 – PureWick™ Male External Catheter IFU PWMX30	36
26.2	Appendix 2 – PureWick™ Urine Collection System IFU PW100 & PW200	36
26.3	Appendix 3 – UltraFlex™ Self-Adhering Male External Catheter IFU 33102, 33302 36	
26.4	Appendix 4 -- End of Study Preference Questionnaire (Sample)	36
26.5	Appendix 5 – PROMIS Sleep Disturbance Short-form 4.....	37

	Title: Clinical Investigation Plan:	Page No: 1 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

1.0 SYNOPSIS

Study Title	A Comparative Crossover Study on the Safety, Efficacy, and Patient Reported Satisfaction of the PureWick™ System with an Established Comparator Overnight in the Home Setting for Incontinence in Adult Males	
Short Title	PUREST-M Pilot	
CIP Number, Version and Date	UCC-23HC013, v1.0, 18-DEC-2024	
Registration	Clinicaltrials.gov	
Sponsor Name and Address	Becton, Dickinson and Company 8195 Industrial Blvd. Covington, GA 30014	
Participating Clinical Sites and Countries	A list of participating clinical sites, Principal Investigators, and the relevant contact information is maintained in the Trial Master File (TMF).	
Study Device	PureWick™ Male External Catheter (PWMX30) PureWick™ Urine Collection System (PW100, PW200)	
Comparator	UltraFlex™ Self-Adhering Male External Catheter	
Stage of Development	Post-market stage	
Background and Rationale	The study will collect clinical and qualitative preference data from adult male participants requiring urine output management overnight in the home setting, the results of which will advise reimbursement in the United States (U.S). This pilot will inform the sample size and the methodology for a future randomized control trial.	
Objectives and Endpoints	Objective(s)	Endpoint(s)
	Primary To compare efficacy and safety of PureWick™ Male System (PureWick™ Male External Catheter & PureWick™ Urine Collection System) and sheath-style male external catheters.	Primary - Efficacy – Daily capture rate via bed pad weights and captured volume. - Safety – Number of device-related Adverse events requiring medical intervention¹ in each treatment group.
	Secondary - To assess participant final preference between the PureWick™ Male System (PureWick™ Male External Catheter & PureWick™ Urine Collection System) and sheath-style male external catheters after treatment completion. - To measure adherence/dislodgement of the study device - To assess the tolerance of PureWick™ over the expected duration of use.	Secondary - End of study preference questionnaire administered at study completion. - Proportion of device wear nights that the device became dislodged. - Number of nights of actual use of each device.
	Exploratory To assess impact of PureWick™ Male System and sheath-style male external catheters on sleep quality related Quality of Life.	Exploratory PROMIS Sleep Disturbance questionnaire at baseline and every 7 days during treatment.

	Title: Clinical Investigation Plan:	Page No: 2 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

¹ i.e., new prescription medication, surgery or procedure, or therapy ordered by a medical provider to treat or manage the adverse event

Study Design	This is a prospective, open-label, randomized, crossover study to evaluate the safety, efficacy, and patient reported satisfaction using the PureWick™ System (PureWick™ Male External Catheter & PureWick™ Urine Collection System) in comparison with the UltraFlex™ Self-Adhering Male External Catheter. Participants are randomized 1:1 to a treatment sequence and will use each device at night for a 7-day period. The primary efficacy endpoint is the mean capture rate. The primary safety endpoint is the number of device-related AEs requiring medical intervention. Capture rates and Adverse Events are assessed daily throughout each 7-day treatment phase. Sleep disturbance is assessed at baseline and every 7 days during treatment. End of study preference questionnaire is completed at the end of treatment. Device adherence is assessed by the proportion of device wear nights that the study device became dislodged. Tolerability is assessed by number of nights of actual device use.
Number of Subjects and Statistical Considerations	Approximately 15 adult male subjects from 2 sites will participate in this pilot study to inform the larger Randomized Clinical Trial (RCT). The sample size is planned based on operational and practical considerations and is adequate for the purpose of this pilot study.
Subject Population	Adult male participants ≥ 65 years of age currently using incontinence products at night for urine output management in the home setting (e.g., nocturnal enuresis, nocturia, mobility limitation) will be recruited for this study by the study sites from their current patient list.
Subject Inclusion/Exclusion Criteria	Inclusion Criteria To be eligible to participate in this study, an individual must meet all the following criteria: 1. Adult male participants ≥ 65 years of age at the time of signing the informed consent 2. Male anatomy at the time of enrollment 3. Currently use diapers, pads, or equivalent at night for urine output management 4. Willing to comply with all study procedures in this protocol 5. Provision of signed and dated informed consent form Exclusion Criteria Participants are excluded from the study if any of the following criteria apply: 1. Has frequent episodes of bowel incontinence; or 2. Has chronic urogenital infections, active genital herpes; or 3. Has Urinary retention; or 4. Has experience using study devices in the home setting within the last year; or 5. Is agitated, combative, and/or uncooperative and may remove the external catheter; or 6. Has any wound, open lesion or irritation on the genitalia, perineum, or sacrum; or 7. Any other condition that, in the opinion of the investigator, would preclude them from participating in the study; or 8. Is considered a vulnerable population.

	Title: Clinical Investigation Plan:	Page No: 3 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Interventions / Measurements / Procedures	In this prospective, open-label, randomized crossover trial, approximately 15 adult men with Nocturnal Urinary Incontinence requiring the use of diapers or pads in bed will be 1:1 randomized to a treatment sequence using two devices (PureWick™ Male External Catheter and UltraFlex™ Self-Adhering Male External Catheter) and followed for approximately 16 days through 2 treatment phases. For purposes of this study, the PureWick™ Male System will be referenced to include the PureWick™ Male External Catheter used in conjunction with the PureWick™ Urine Collection System, including the tubing and the canister. At the start of the study, participants will be consented and screened against inclusion/exclusion criteria. All subjects that have met all eligibility criteria will be assigned a treatment order. Participants will receive a demo of the study devices at the time of consent. Once enrolled, participants will complete an anatomical measuring procedure to determine sizing for the UltraFlex™ Self-Adhering Male External Catheter. During the baseline visit, participants will view a training video/ review the IFU for the applicable product at the beginning of each treatment phase and have access to the Instructions for Use (IFU) to review. Participants will use the device assigned in treatment phase 1 overnight while sleeping for 1 week (7 days) before transitioning to the second assigned device in treatment phase 2. A minimum 2-day washout period will occur between treatment phases. The primary endpoints will evaluate safety (adverse events requiring medical intervention) and efficacy (capture rate). Safety will be evaluated based on the number of device-related adverse events requiring medical intervention (i.e., new prescription medication, surgery or procedure, or therapy ordered by a medical provider to treat or manage the adverse event) in each treatment group, and efficacy will be measured based on daily capture rate. Nurses will visit the patients' homes daily to collect endpoint data. Nurses will also visually assess skin irritation and assign a score using the Draize Scale. If during the skin assessment a Draize score of 4 is documented on the skin irritation scale in any category, it must be recorded as an AE and will require participants to discontinue from the treatment phase. Any other score on the skin irritation scale in any category may be recorded as an AE based on PI discretion. The secondary outcomes include participant evaluation of the study devices via an end of study preference questionnaire, device adherence, and device tolerability measured by number of nights of actual device use.
Duration of Study Participation	The total expected duration of subject participation is approximately 18 days from consent through last study visit.
Clinical Sites	Approximately 2 sites in the United States (U.S.)
Study Timeline	Planned enrollment period: February 2025 – June 2025
Data Monitoring Committee	No Data Monitoring Committee (DMC) will be used.
Clinical Events Committee	No Clinical Events Committee will be used.
Regulatory Status	Post-Market PureWick™ Male System: Class I, non-sterile, 510(k) exempt device currently marketed in the U.S. This investigation will use the PureWick™ System for its intended purpose per the IFU.

2.0 ABBREVIATIONS

Abbreviations	Term
AE	Adverse Event
ADE	Adverse Device Effect
ASADE	Anticipated Serious Adverse Device Effect
BD	Becton, Dickinson and Company

	Title: Clinical Investigation Plan:	Page No: 4 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

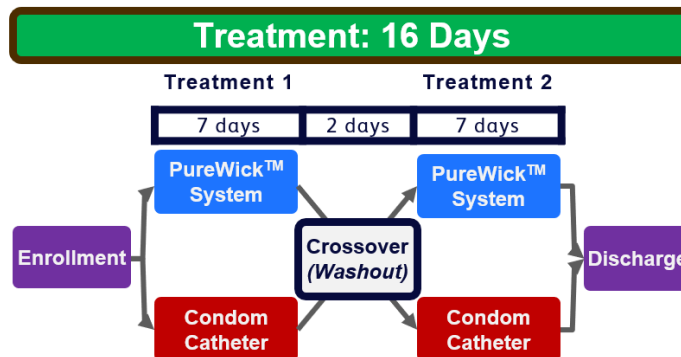
Abbreviations	Term
BMI	Body Mass Index
CFR	Code of Federal Regulations
CI	Confidence Interval
CIP	Clinical Investigation Plan
CRF	Case Report/Record Form
CRO	Contract Research Organization
DMC	Data Monitoring Committee
EDC	Electronic Data Capture
EU MDR	European Medical Device Regulation
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act of 2007
GCP	Good Clinical Practice
GDPR	Generate Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IFU	Instructions for Use
IRB/EC	Institutional or Independent Review Board/Ethics Committee
ISO	International Organization for Standardization
MEC	Male External Catheter
MM	Medical Monitor
PI	Principal Investigator
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
TMF	Trial Master File
USADE	Unanticipated Serious Adverse Device Effect

	Title: Clinical Investigation Plan:	Page No: 5 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

3.0 STUDY SCHEDULE

3.1 Study Schema



3.2 Schedule of Activities

	On-Site Visit	Treatment 1 (In-Home Assessments)			Treatment 2 (In-Home Assessments)		
Assessment	Screening/ Enrollment	Baseline	Night 1-7 (Device Use)	Washout Period (2 Days ¹)	Baseline (Crossover)	Nights 1-7 (Device Use)	End of Treatment
Device Demonstration ²	X						
Informed Consent	X						
Inclusion & Exclusion Criteria	X						
Demography	X						
Medical History	X						
Participant ID Assignment and Treatment Order Randomization	X						
Introduction of Home Nurse (On-Site)	X						
Participant Self-Reported Skin Assessment	X						
Participant to Complete Anatomical Measurement	X						
Nocturnal Enuresis (NE) attribute survey	X						
Nurse Visual Skin Assessment & Draize Scoring		X	X		X	X	
Nurse Confirm Study Supplies		X			X		
Participant to View Device Training Video and/or Instruction for Use (IFU)		X			X		
Nurses takes Pre-weight		X	X		X	X	

	Title: Clinical Investigation Plan:	Page No: 6 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

	On-Site Visit	Treatment 1 (In-Home Assessments)			Treatment 2 (In-Home Assessments)		
Assessment	Screening/ Enrollment	Baseline	Night 1-7 (Device Use)	Washout Period (2 Days ¹)	Baseline (Crossover)	Nights 1-7 (Device Use)	End of Treatment
Participant wears device overnight			X			X	
Nurse takes post-weight			X			X	
Nurse documents Device Dislodgement			X			X	
Nurse administers PROMIS Sleep Disturbance Questionnaire		X		X ³			X ³
End of Study Preference Questionnaire ⁴							X
Nurse completes End of Study Disposition							X
AE/SAE Review ⁵							
Device Deficiencies ⁵							

1 -- Minimum of 2 days for the washout period. If the participant has a skin issue, the washout period can be extended up to 7 days. The nurse should call the participant to confirm if the skin issue was resolved prior to scheduling the Treatment 2 Baseline visit

2 --To occur prior to consenting the participant

3 -- PROMIS Sleep Disturbance questionnaire to be completed after device use night 7 in each treatment phase

4 -- To be completed at completion or discontinuation of treatment phase 2. Questionnaire should only be completed if each device was used for at least one night

5 - Collect if applicable

4.0 INTRODUCTION

4.1 Background

Nocturnal enuresis, or overnight urinary incontinence, is a significant concern among men, particularly as they age. Studies indicate that the prevalence of urinary incontinence in men ranges widely, with various factors contributing to its occurrence. Urinary incontinence affects a substantial portion of the male population, with future directions focusing on better management and treatment options¹. Furthermore, cognitive impairment or dementia significantly increases the risk of incontinence, emphasizing the need for targeted interventions in these groups². Urinary incontinence in home care settings not only affects the quality of life but also presents severe challenges in daily living³. There is a profound impact of urinary incontinence on the lives of elderly men, as it can lead to social isolation and decreased quality of life.⁴ These findings collectively underscore the importance of addressing nocturnal enuresis through comprehensive and individualized care strategies.

Current management options for male incontinence at home include behavioral techniques, lifestyle modifications, and medical interventions. Absorbent products and traditional external catheters are practical solutions for managing incontinence in home care settings, although they may impact the quality of life³. Traditional sheath style male

	Title: Clinical Investigation Plan:	Page No: 7 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

external catheters may not be effective for all males. Medications such as anticholinergics and desmopressin as effective in reducing urinary frequency and urgency.⁵ However, these management options can have drawbacks, including serious side effects from medications, the inconvenience of using absorbent products, and the psychological impact of living with incontinence⁴. These challenges underscore the need for individualized care strategies to effectively manage male incontinence at home.

Difficult-to-manage urinary incontinence in men in the home setting poses health risks and can lead to severe consequences. It has long been understood that urinary incontinence is associated with increased risks of hospitalization, nursing home admission, and mortality⁶. This underscores the critical need for effective management strategies to prevent these adverse outcomes. Similarly, it has been reported that urinary incontinence is linked to a higher likelihood of death, nursing home admission, and functional decline⁷. These findings highlight the importance of addressing urinary incontinence promptly and effectively to mitigate its impact on overall health and quality of life. Without proper management, individuals may experience complications such as skin injury, falls, and a decline in mental health due to the stress associated with incontinence for these patients and their caregivers.

4.2 Rationale

The study will collect clinical and qualitative preference data from adult male patients requiring urine output management overnight in the home setting, the results of which will advise reimbursement in the United States (U.S.). This pilot will inform the sample size and the methodology for a future randomized control trial.

5.0 IDENTIFICATION AND DESCRIPTION OF THE STUDY DEVICE

5.1 Study Device(s)

PureWick™ Male External Catheter (PWMX30)

Study participants will be evaluating the PureWick™ Male External Catheter (Figure 2). The PureWick™ Male External Catheter is intended for non-invasive urine output management in users with male anatomy. This device is a Class I, 510k exempt device which is marketed in the United States. The device Instructions for Use (IFU) can be found in Appendix 1. This protocol shall strictly adhere to the device instruction for home care as specified in the Instructions for Use (IFU).

Male participants will use the PureWick™ MEC overnight for 7 days. The study will utilize approximately 105 PureWick™ MECs, 7 per participant.

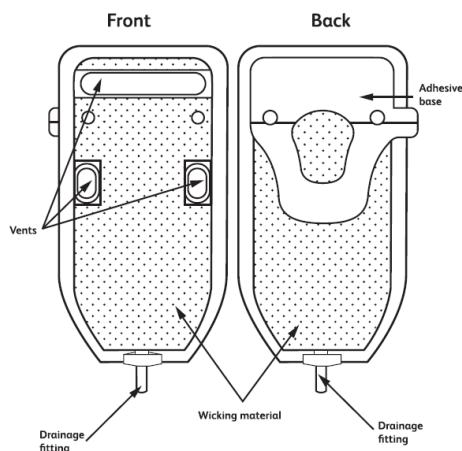
All PureWick™ MECs will be shipped to the study site from regular commercial stock. Access to the devices will be limited to study staff and will only be used by study participants who have provided written informed consent.

Pre-placement procedure:

Prior to placing the PureWick™ MEC, perineal care should be performed, and skin should be assessed for integrity.

	Title: Clinical Investigation Plan:	Page No: 8 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

**Figure 1****Comparator:** UltraFlex™ Self-Adhering Male External Catheter (33102, 33302)

The UltraFlex™ Self-Adhering Male External Catheter will be used as the comparator for this study. The device is a self-adhering male external catheter used for drainage of urine. The catheter is applied by the patient or caregiver. The self-adhering male external catheter is designed for the management of adult male urinary incontinence. In this study, the device will be used according to the current IFU in Appendix 3.

All UltraFlex™ Self-Adhering Male External Catheters will be shipped to the study site from regular commercial stock. Access to the devices will be limited to study staff and will only be used by study participants who have provided written informed consent.

**Figure 2**

	Title: Clinical Investigation Plan:	Page No: 9 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

5.1.1 Device Labeling

All study devices are commercially available and will be supplied as labeled by the manufacturer. Copies of the study device's labeling will be maintained under a separate cover.

5.2 Equipment to be Used in Study

PureWick™ Urine Collection System (PW100, PW200)

The PureWick™ Urine Collection System (PUCS) (Figure 4) is to be used with the PureWick™ Male External Catheters which are intended for non-invasive urine output management. The PUCS pulls voided urine through tubing that is connected to a collection canister. Urine is stored in the collection canister for proper disposal (see Figure 3). In this study, the device will be used according to the current IFU in Appendix 2. The PUCS is a Class 1, 510(k) exempt, non-sterile device.

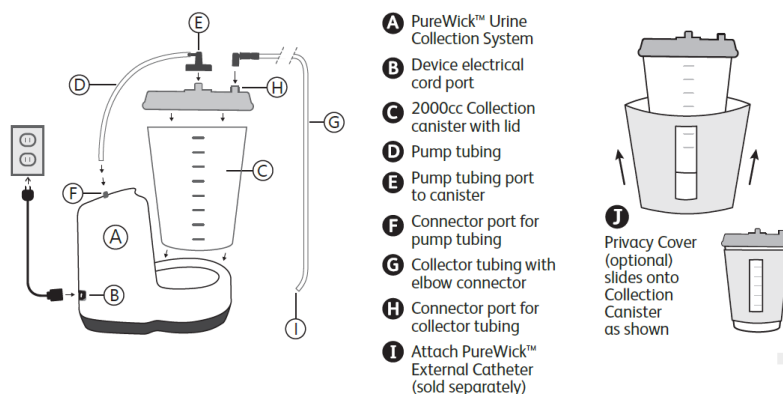


Figure 3

6.0 OBJECTIVES AND HYPOTHESES

6.1 Objectives and Endpoints

Objective Type	Objective	Endpoint
Primary	To compare efficacy and safety of PureWick™ Male System (PureWick™ Male External Catheter & PureWick™ Urine Collection System) and sheath-style male external catheters.	- Efficacy – Daily capture rate via bed pad weights and captured volume. - Safety – Number of device-related Adverse events requiring medical intervention in each treatment group.
Secondary	To assess participant device satisfaction and preference between the PureWick™ Male System (PureWick™ Male External Catheter & PureWick™ Urine Collection System) and sheath-style male external catheters after treatment completion.	End of study preference questionnaire administered at study completion.

	Title: Clinical Investigation Plan:	Page No: 10 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

	- To measure study device adherence/dislodgement - Tolerability - To assess the tolerance of PureWick™ System and sheath-style male external catheters over the expected duration of use.	- Proportion of device wear nights that the device became dislodged. - Number of nights of actual use of each device.
Exploratory	To assess impact of PureWick™ Male System and sheath-style male external catheters on sleep quality related Quality of Life.	PROMIS Sleep Disturbance score collected at baseline and every 7 days during treatment.

6.2 Performance Goal

Not applicable

7.0 DESIGN OF THE STUDY

7.1 Study Design and Justification

In this prospective, open-label, crossover trial, approximately 15 men with Nocturnal Urinary Incontinence requiring the use of diapers or pads in bed will be 1:1 randomized to a treatment sequence using two devices (PureWick™ MEC and UltraFlex™ Self-Adhering Male External Catheter) and followed for approximately 16 days through 2 treatment phases. For purposes of this study, the PureWick™ Male System will be referenced to include the PureWick™ Male External Catheter used in conjunction with the PureWick™ Urine Collection System, including the tubing and the canister.

At the start of the study, participants will be consented and screened against inclusion/exclusion criteria. Participants that have met all eligibility criteria will be assigned a participant ID treatment order. Participants will complete an anatomical measuring procedure to determine sizing for the UltraFlex™ Self-Adhering Male External Catheter at the baseline visit. Participants will view the training video and/or review the IFU for the applicable product at the beginning of each treatment phase and have access to the Instructions for Use (IFU) to review. Participants will use the device assigned in treatment phase 1 overnight while sleeping for 1 week (7 days) before transitioning to the second assigned device in treatment phase 2. Prior to treatment phase 2, participants will have a washout period for a minimum of 2 days.

The primary objectives are to evaluate safety (device related adverse events requiring medical intervention) and efficacy (daily capture rate). Safety will be evaluated using incidence rate of AEs requiring medical intervention and efficacy will be measured based on daily capture rate.

Nurses will visit patients' homes daily to assess primary endpoints and collect data. The nurses will also assess skin irritation daily using the Draize Scale.

The secondary objectives are to assess participants' satisfaction with and preference between the PureWick™ Male External Catheter and sheath-style male external catheters after treatment completion, device adherence/dislodgement, and device tolerance over the expected duration of use.

	Title: Clinical Investigation Plan:	Page No: 11 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

The exploratory objective will assess the impact of PureWick™ Male System and sheath-style male external catheters on sleep quality using self-reported PROMIS Sleep Disturbance assessments.

This study will assess the performance of, and participant reported satisfaction with the PureWick™ System in the home setting. The endpoints chosen for the study were selected based on peer-reviewed research and feedback from expert consultants, Centers for Medicare & Medicaid Services, applicable health authorities and urology key opinion leaders.

7.2 Treatment Allocation and Measures to Minimize Bias

This is an open-label, cross over study in which each participant will be randomized to a device sequence. All male participants will evaluate the PureWick™ MEC and the UltraFlex™ Self-Adhering Male External Catheter. The procedures are the same in both treatment phases of the study.

7.2.1 Randomization

Randomization will occur after informed consent is obtained and after the study personnel ensures the participant meets all eligibility criteria. Participants will be randomized to a 1:1 to one of two treatment sequence. Randomization envelopes will be provided by the Sponsor to the clinical site.

7.2.2 Blinding/Masking

Not applicable. This is an open-label study.

7.2.2.1 Procedures for Unblinding

Not applicable

7.3 Potential Influencing or Confounding Factors and Bias

Standardized questionnaires and data collection tools will be used to assess participant experience and to document study findings, respectively. As training level and device experience could be a foreseeable factor that could impact study outcomes, standardized instruction will be used to train all participants on device use.

The methodology for measuring urine capture rates have been standardized wherever possible across both devices. All participants will use both the PureWick™ MEC and the UltraFlex™ Self-Adhering Male External Catheter.

7.4 End of Study Definition

A participant is considered to have completed the study if they have completed all treatment visits of the study, including end of treatment visit, shown in the Schedule of Activities (section 3.2).

8.0 BENEFITS AND RISKS OF THE STUDY DEVICE, CLINICAL PROCEDURE(S), AND THE STUDY

Participants in this study will be treated with both the PureWick™ Male External Catheter and the UltraFlex™ Self-Adhering Male External Catheter. Both devices are marketed in the US. Therefore, participants will be exposed to the same risks shared by all patients using these devices.

	Title: Clinical Investigation Plan:	Page No: 12 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

More detailed information about the known and expected benefits and risks and reasonably expected adverse events/adverse device effects of PureWick™ MEC and UltraFlex™ Self-Adhering Male External Catheter may be found each product IFU .

8.1 Benefit Assessment

Potential benefits to participants using the PureWick™ System may include:

- The PureWick™ System is easy to set up and can be placed in a few easy steps.
- Participants receive enhanced follow up, including daily skin assessments and urine output management by a nurse.
- Participants contribute to the process of generating clinical evidence for urine output management solution in the home setting.
- Potential to benefit from future reimbursement of the PureWick™ System.

8.2 Risk Assessment

8.2.1 Anticipated Adverse Device Effects and Anticipated Procedure-related Adverse Events

Potential Risk of Clinical Significance	Summary of Data/Rational for Risk	Mitigation Strategy
PureWick™ Male External Catheter		
• Skin Injury • Skin Irritation • Allergic reaction • Infection • Discomfort • Broken skin from trimming/shaving	PureWick™ MEC is an external device placed around the base of the penis and adhered to the pelvic skin.	• To avoid potential skin injury, never pull the device directly away from the patient. Always peel in the direction from head to foot. • Perform perineal care using the included wipes and assess skin integrity before device application. • Replace the device every 24 hours or if soiled with feces, blood, or semen. • Remove the device prior to ambulation. • Participants will be provided with new, unused trimmers and guards for use during the study.
Exposure to biohazard or blood borne pathogens	Device is intended to capture urine, may lead to transmission of bloodborne pathogens	The nurse and or caregiver will wear gloves when handling devices and will dispose of used devices per the IFU.
UltraFlex™ Self-Adhering Male External Catheter		

	Title: Clinical Investigation Plan:	Page No: 13 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Potential Risk of Clinical Significance	Summary of Data/Rational for Risk	Mitigation Strategy
• Infection • Skin Injury • Skin Irritation • Allergic reaction • Swelling • Numbness • Discomfort • Pain • Discoloration • Abnormal appearance	The UltraFlex™ self-adhering Male External Catheter is placed at the end of the penis.	Participants should not use the device if an allergic reaction occurs to know device components. For good hygiene, change catheter daily. User should not use the device for periods longer than 24 hours.
Exposure to biohazard or blood borne pathogens	Device is intended to capture urine, may lead to transmission of bloodborne pathogens.	The nurse and or caregiver will wear gloves when handling devices and will dispose of used devices per the IFU.
PureWick™ Urine Collection System		
• Choking • Strangulation • Electrical Shock • Injury from Explosion • Chemical Burns	The PureWick™ Urine Collection System is to be used with PureWick™ External Catheters which are intended for non-invasive urine output management.	• Keep small device parts, cords and tubing out of reach of children. • Always unplug PureWick™ Urine Collection System before cleaning or when not in use. • DO NOT IMMERSE THE PUREWICK™ URINE COLLECTION SYSTEM IN WATER. As with most electrical devices, electrical parts in this system are electrically live even when the power is off. To reduce the risk of electric shock, if the PureWick™ Urine Collection System falls into water, unplug immediately. DO NOT REACH INTO THE WATER TO RETRIEVE IT. • Do not use PureWick™ Urine Collection System in oxygen rich environments or in conjunction with flammable anesthetics
Exposure to biohazard or blood borne pathogens	Device is intended to capture urine, may lead to transmission of bloodborne pathogens.	The nurse and or caregiver will wear gloves when handling devices and will dispose of used devices per the IFU.

8.2.2 Additional Risks Associated with Study Participation

Potential Risk	Summary of Data/Rational for Risk	Mitigation Strategy
• Sponsor exposure to Patient Health Information	Study data, including photographs if applicable, will be collected in the	Access controlled Secure File Transfer Protocol (SFTP) software will be used to transfer data.

	Title: Clinical Investigation Plan:	Page No: 14 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Misplaced/Loss of confidentiality of information	home setting and transferred to the study site for capture in the clinical database.	
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8.3 Risk / Benefit Analysis

Participants in this study will be treated with approved, marketed devices and will use the investigational devices as intended. Therefore, participants will be exposed to the same risks shared by all patients using these devices for urine output management in a real-world setting.

More detailed information about the study devices and their known and expected benefits, risks, and reasonably expected adverse events of the PureWick™ MEC, PureWick™ Urine Collection System, and UltraFlex™ Self-Adhering Male External Catheter may be found in the Instructions for Use for each product.

Taking into consideration the measures to minimize risk to participants in this study, the potential risks identified in association with PureWick™ System and UltraFlex™ Self-Adhering Male External Catheter are justified by the anticipated benefits that may be afforded to subjects with Nocturnal Urinary Incontinence.

9.0 SUBJECTS

Adult male participants requiring urine output management overnight in the home setting will be recruited for this study by the study site from their current patient list. Study sites may advertise and recruit new patients if eligible participants from the patient list have been exhausted.

To best mimic potential users of the PureWick™ System, participants ≥ 65 years of age will be enrolled.

9.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Adult male participants ≥ 65 years of age at the time of signing the informed consent
- Male anatomy at the time of enrollment
- Currently use diapers, pads, or equivalent at night for urine output management
- Willing to comply with all study procedures in this protocol
- Provision of signed and dated informed consent form

9.2 Exclusion Criteria

Subjects are excluded from the study if any of the following criteria apply:

- Has frequent episodes of bowel incontinence; or
- Has chronic urinogenital infections, active genital herpes; or
- Has Urinary retention; or
- Has experience using study devices in the home setting within the last year; or

	Title: Clinical Investigation Plan:	Page No: 15 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

5. Is agitated, combative, and/or uncooperative and may remove the external catheter; or
6. Has any wound, open lesion or irritation on the genitalia, perineum, or sacrum; or
7. Any other condition that, in the opinion of the investigator, would preclude them from participating in the study; or
8. Is considered a vulnerable population.

9.3 Vulnerable Subjects

No vulnerable populations will be enrolled in the study.

9.4 Point of Enrollment

The point of enrollment is the time at which, following recruitment and before any clinical investigation-related procedures are undertaken, a subject signs and dates the informed consent form.

9.4.1 Point of Randomization

The point of randomization is the time at which a participant has signed consent and met all eligibility criteria

9.4.2 Point of Treatment

The point of treatment is the time at which the home care nurse confirms the following during the participant's baseline in home assessment.

- Participant has the correct study device per randomization treatment sequence.
- Participant has a Draize Score of zero.
- If participant does not have a Draize Score of zero, the participant should be screen failed according to exclusion criteria #6.

9.5 Screen Failures and Replacement of Subjects

Screen failures are defined as participants who consent to participate in the clinical study but do not subsequently meet eligibility criteria prior to treatment. Data collected for screen failures will include consent, criteria leading to exclusion and AEs.

Individuals who do not meet the criteria for participation in this study (screen failure) may be rescreened if the exclusionary criteria are temporary in nature and may resolve over time (e.g., active infection, open wound, etc.). Rescreened participants will be assigned new participant number.

The Principal Investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

9.5.1 Replacement of Subjects

Not applicable.

9.6 Study / Participation Duration

It is expected to take approximately 5 months to complete subject enrollment. The total duration of the study is expected to be 6 months (last subject, last visit).

	Title: Clinical Investigation Plan:	Page No: 16 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

The duration of study participation for an individual subject is expected to be 2.5 weeks treatment through last visit).

9.7 Subject Discontinuation / Withdrawal [and Discontinuation of Intervention]

9.7.1 Discontinuation / Withdrawal

A subject may withdraw from the study at any time at their own request or may be withdrawn at any time at the discretion of the Principal Investigator (PI) or sponsor for safety, behavioral, compliance, or administrative reasons. This is expected to be uncommon.

At the time of discontinuing from the study, no further assessments will be performed.

If the subject withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.

If a subject withdraws from the study, the reason for withdrawal must be documented.

If a participant withdraws from the study, participant will be asked to report any discomfort or voiding issues occurring within the first 24 hours after discharge from the study to the PI or Sponsor

9.7.2 Lost to Follow-Up

A subject will be considered lost to follow-up if they repeatedly fail to return for/complete scheduled visits and is unable to be contacted by the home care nurse or clinical site.

The following actions must be taken if a subject fails to return for/complete a required study visit:

The clinical site or home care nurse must attempt to contact the subject and reschedule the missed visit as soon as possible and counsel the subject on the importance of maintaining the assigned visit schedule and ascertain whether or not the subject wishes to and/or should continue in the study.

Before a subject is deemed lost to follow up, the investigator or designee must make every effort to regain contact with the subject [(where possible, 3 telephone calls and, if necessary, a certified letter to the subject's last known mailing address or local equivalent methods)]. These contact attempts should be documented in the subject's medical record.

Subject will be considered lost to follow-up on the date of the final failed contact attempt.

9.8 Subject Compensation

Participants will be compensated for their time and inconvenience. For participants who do not complete the study in its entirety, subject stipends will be prorated according to the completed visits or procedures.

10.0 PROCEDURES

	Title: Clinical Investigation Plan:	Page No: 17 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Study procedures and their timing are summarized in the Study Schema and Schedule of Activities (Section 3.1 and 3.2). CIP waivers or exemptions are not allowed. Adherence to the study design requirements, including those specified in the CIP, is essential and required for study conduct.

All screening evaluations must be completed and reviewed to confirm that potential subjects meet all eligibility criteria. The investigator will maintain a screening log to record details of all subjects screened and to confirm eligibility or record reasons for screening failure, as applicable.

10.1 Screening Procedures

10.1.1 Informed Consent

The background and purpose of the study, participation requirements, and the potential benefits and risks of the procedure(s) must be explained to the subject in layman's terms. Prior to the conduct of any protocol-specific procedures, including any procedure required to determine subject eligibility, the subject must voluntarily provide Informed Consent. Documentation of the Informed Consent process along with the signed Informed Consent Form should be present with the subject's source documents and dated prior to initiation of study-specific procedures.

10.1.2 Eligibility

The participant's eligibility (inclusion/exclusion criteria) for study participation will be confirmed by the PI or designee (via on site or remote visit) per investigational site policy and documented on the appropriate electronic case report form (eCRF).

10.2 Medical History / Baseline Assessments

Participant baseline and demographic information, including, but not limited to age, sex assigned at birth, primary diagnosis, medical history, and self-reported height and weight, sleep position, and recorded after informed consent is obtained prior to device use.

10.3 Enrollment

Participants who sign an informed consent will be considered enrolled in this study.

A unique identification number will be given to study participants. Participant numbers will be assigned in sequential order. The participant number will consist of six digits. The first three digits will designate the site number, and the last three digits will designate the participant number in sequential order.

10.4 Randomization

Randomization will occur after informed consent is obtained and after study personnel ensures the participant meets all eligibility criteria. Participants will be randomized 1:1 to a treatment sequence using two devices which are the PureWick™ Male System and the UltraFlex™ Self-Adhering Male External Catheter. The study site will receive randomization envelopes developed by the Sponsor statistics team.

10.5 Home Care Nurse Introduction

The principal investigator or their designee will introduce enrolled participants to the nurse that will conduct home visits (either in person or virtually).

Nurse and participant will arrange the in-home baseline visit. Once a baseline visit has been scheduled, the site coordinator/pharmacist will arrange study device delivery from clinical site to the participant's home.

	Title: Clinical Investigation Plan:	Page No: 18 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

10.6 Efficacy Assessment(s) – Urine Capture

For In-home assessments, urine weights (in grams) will be collected and documented by the home care nurse before and after each night of device use.

10.6.1 Weights prior to device use (pre-weights)

10.6.1.1 PureWick™ Male External Catheter

During the PureWick™ MEC treatment phase, the nurse will collect and document weights for the following:

- Empty PureWick™ collection canister with the lid (without tubing attached)
- Unused absorbent bed pad(s) in a sealed 2-gallon bag

10.6.1.2 UltraFlex™ Self-Adhering Male External Catheter

During the UltraFlex™ Self-Adhering Male External Catheter treatment phase, the nurse will collect and document weights for the following:

- Unused urine collection bag with tubing attached in empty canister (no lid)
- Empty graduated cylinder
- Unused absorbent bed pad(s) in a sealed 2-gallon bag.

10.6.2 Weights after device use (post-weights)

10.6.2.1 PureWick™ Male External Catheter

For the PureWick™ system, the nurse will collect and document weights for the following:

- The PureWick™ collection canister with captured urine and lid (without tubing attached)
- Used absorbent bed pad(s) in a sealed 2-gallon bag

10.6.2.2 UltraFlex™ Self-Adhering Male External Catheter

For the UltraFlex™ Self-Adhering Male External Catheter, the nurse will collect and document weights for the following:

- Used urine collection bag with tubing attached in canister (no lid)
- Graduated cylinder with captured urine
- Used absorbent bed pad(s) in a sealed 2-gallon bag

10.6.3 Safety Assessment

For in-home assessments during treatment phase 1 and treatment phase 2, the nurse will capture all adverse events identified or participant-reported. The nurse will also conduct a visual skin assessment and score skin condition using the Draize scale (Table 1).

If during the skin assessment a Draize score of 4 is documented on the skin irritation scale in any single category, it must be recorded as an AE and will require participants to discontinue from the treatment. Any other score on the skin irritation scale in any category may be recorded as an AE based on PI discretion.

	Title: Clinical Investigation Plan:	Page No: 19 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

To assess a potential AE identified during the home visit, the nurse will contact the PI or designee. The site will document the AE assessment on the appropriate CRF from and follow the AE until resolution. If the PI requests a follow up visit with the participant, this can be conducted on site or virtually per investigational site policy.

During the skin assessment, at the nurse's discretion a photograph of the skin in the device application area may be taken for PI review and assessment. The photo will be sent in a pseudonymized matter to the site, only the subject ID and the date when the picture was taken will be collected. These photographs will be shared with the Principal Investigator / Sub-Investigator, the Sponsor, and the study staff only and will be used for the Principal Investigator / Sub-Investigator's review and assessment of the skin reactions.

10.6.3.1 Draize Scale for Skin Irritation

Score	Erythema (redness)	Edema (swelling)	Bleeding
0	None	None	None
1^a	Very slight (barely perceptible) erythema	Very slight (barely perceptible) skin surface rise	Just a visible spot of red
2^a	Well-defined erythema	Well-defined skin surface rise (edges of area well-defined by definite raising)	A drop of red blood
3^a	Moderate erythema	Moderate skin surface rise	A continuing ooze of red blood
4^b	Severe (beet red) or damage to skin (eschar formation)	Severe skin surface rise	Significant bleeding from the sight

^a A rating of 1-3 on the skin irritation scale in any category may be recorded as an AE based on PI discretion.

^b A rating of 4 on the skin irritation scale in any single category must be recorded as an AE and will require participant treatment discontinuation

10.7 Baseline

This part of the study is to assess if the participants are eligible to begin treatment per assigned treatment sequence. During the baseline assessment urine output measurements will not be taken.

The nurse will collect nighttime routine (e.g., sleep position) and visually assess for any existing signs of irritation, using the Draize Scale Skin Scoring system.

	Title: Clinical Investigation Plan:	Page No: 20 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

The nurse will also confirm the participant has all study supplies for the 1st treatment. The participant must review the training video and/or IFU. The nurse will also collect the PROMIS sleep disturbance questionnaire.

If Skin Score is Greater than 0:

1. Participant is considered a screen failure,
2. Participant may be rescreened and assigned a new subject number once skin irritation resolves,
3. Nurse will notify PI and Site staff will complete appropriate eCRFs.

If Skin Score is 0:

1. Nurse will have participant complete PROMIS Sleep Disturbance assessment.
2. Nurse will confirm treatment assignment.
3. Nurse will provide device and procedure training via standardized product training.
4. Once training is completed, nurse will ensure the participant have all the supplies prepped for the first night of device wear.
5. Nurse will collect and document all pre-weights (section 10.6.1)

10.8 Device Use Nights 1-7 (Treatment 1 & Treatment 2)

1. Participant self-places device prior to sleep, records device placement time and uses device overnight.
2. Upon waking the next day, participant self-removes device after sleep and records device removal time.
3. Participant will manage the removed study device as follows based on treatment sequence assignment:
 - a. PureWick™ MEC – disconnect PW MEC from tubing and cannister and dispose of the used device.
 - b. UltraFlex™ Self-Adhering Male External Catheter – drain any residual urine from the UltraFlex™ MEC and tubing into the urine collection bag. Once drained as best as possible, participant discards the UltraFlex™ MEC. Urine collection tubing should be clamped or tied to prevent urine spillage. Participant leaves tubing and urine collection bag as is for nurse to capture weight.
4. Participant places the used bed pads in their respective, pre-weighed sealed bags.
5. Upon arrival for home visit, the nurse will weigh and document post-weights (see section 10.6.1.3) and device placement and removal times.
6. The nurse will document if the device became dislodged during the prior night wear.
7. The nurse will perform a visual skin assessment and note any signs of skin irritation or injury and complete the Draize Scale assessment and documents the score (see section 10.6.3.1).
8. Nurse preps for the next night of device wear.
9. Nurse and participant schedule next day visit.

	Title: Clinical Investigation Plan:	Page No: 21 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

10.9 Wash-out Period

All participants will have a minimum of 2 days for the washout period in between treatments. If needed due to skin injury or irritation, the washout period can be extended to a maximum of 7 days. In the case of an extended washout, the nurse must call the participant to confirm any skin issue has resolved. Once resolved, the nurse will schedule the treatment 2 baseline visit. The nurse may consult with the PI as needed.

10.10 End of Treatment

After device use night 7 in treatment 2, the nurse will collect the final PROMIS sleep disturbance questionnaire. The nurse will also administer the end of study preference questionnaire to participants that used each device for at least one night each. Lastly, the nurse will complete the End of Study Disposition.

Prior to concluding the End of Treatment visit, the nurse should collect and return any unused study devices and supplies and dispose of all used study products at the patient's home.

Participants will be reminded to report any discomfort or voiding issues occurring within the first 24 hours after study completion.

11.0 STATISTICAL METHODS

The Statistical Analysis Plan (SAP) will be finalized prior to database lock and will include a more technical and detailed description of the statistical analyses described in the following sections. This section includes a summary of the planned statistical analyses of the most important endpoints including primary and key secondary endpoints.

11.1 Sample Size Considerations

Approximately 15 participants will be enrolled. The sample size is planned based on operational and practical considerations and is adequate for the purpose of this pilot study.

11.2 Analysis Population

The analysis populations will be defined as follows for this study:

Population	Description
Enrolled	All subjects who sign the ICF
Intent-to-Treat (ITT)	Subjects who signed ICF and randomized to a treatment sequence.
Per-Protocol (PP)	ITT subjects without major protocol deviation

ITT population will be used for the analyses of endpoints. Sensitivity analyses may be conducted using PP population.

11.3 General Considerations

- Handling of Missing Data

	Title: Clinical Investigation Plan:	Page No: 22 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Endpoint data may be missing due to reasons including lost to follow-up or withdrawal of consent. Reason for missing endpoints will be reported. For the primary efficacy endpoint, if capture rate assessments are missing for part of the study period, derivation of the primary efficacy endpoint will be based on available data.

- Comparability of Groups

Baseline characteristics and potential confounders will be compared between treatment sequence groups. Subgroup analysis or regression may be used if potential confounding effect is suspected.

- Poolability of Data

The effect of investigational site will be evaluated using regression models, with primary endpoint as the dependent variable, and treatment, investigational site, and the interaction term between treatment and investigational site as fixed effects.

- Multiplicity Control

No formal hypothesis test is planned for this pilot study. P values and confidence intervals may be provided for exploratory purposes and are unadjusted for multiplicity.

11.4 Final Analysis

11.4.1 Primary Endpoint(s)

11.4.1.1 Primary Efficacy Endpoint

Capture rate is evaluated daily during participant treatment phase 1 and treatment phase 2. Daily capture rate is defined as:

$\text{captured urine weight} / (\text{captured urine weight} + \text{leaked urine weight})$

The primary efficacy endpoint is derived by computing the mean of daily capture rate for each treatment. Descriptive statistics of the primary efficacy endpoint, including mean, standard deviation, median, and range will be provided by treatment. The paired difference in mean daily capture rate between treatments will be provided.

11.4.1.2 Primary Safety Endpoint

The primary safety endpoint is derived by counting the number of device-related adverse events requiring medical intervention for each treatment. Descriptive statistics of the primary safety endpoint, including mean, standard deviation, median, and range will be provided by treatment. Paired difference in the number of device-related adverse events between treatments will be provided.

11.4.2 Secondary Endpoint(s)

11.4.2.1 End of Study preference questionnaire

Items in the questionnaire will be summarized as categorical variables (using frequency count and percentage).

11.4.2.2 Proportion of device wear nights that the device became dislodged

The proportion of device wear nights that the device became dislodged will be summarized using descriptive statistics by treatment. Paired difference between treatment will be provided.

	Title: Clinical Investigation Plan:	Page No: 23 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

11.4.2.3 Tolerability - Number of nights of actual use of each device

The number of nights of actual use will be summarized using descriptive statistics by treatment. Paired difference between treatments will be provided.

11.4.3 Tertiary/Exploratory Endpoint(s)

11.4.3.1 Questionnaire PROMIS Sleep Disturbance

Items in the questionnaire will be summarized both as categorical variables (using frequency count and percentage) and as continuous variables (using mean, standard deviation, median, and range) by treatment.

11.4.4 Other Analyses

Not Applicable

11.5 Interim Analysis

Not Applicable

12.0 DATA MANAGEMENT

Data management is the responsibility of the Sponsor. Data from completed CRFs will be managed in a secured, controlled database. A Data Management Plan (DMP) will be developed that outlines the end-to-end process of data collection, data processing and reconciliation, and database lock. Procedures for validations and data storage will also be contained within the DMP.

12.1 Case Report Forms

The Principal Investigator is responsible for ensuring the completeness and accuracy of all study documentation.

All required clinical data will be collected/documented in sponsor-provided electronic Case Report Forms (CRFs). Corrections should be made using the principles of Good Documentation Practice. FDA 21 CFR 11 is followed as well as other applicable legislation on the handling of electronic data.

Clinical site numbers and subject numbers will be used to track subject information throughout the study. [Subject personal information will be pseudonymized/de-identified.

12.2 Source Documentation

Source documentation is required to be maintained by the clinical site. Original or certified copies of all relevant clinical findings, observations, and other activities throughout the study must be recorded and maintained by the clinical site.

12.3 Record Retention

The Investigator shall retain all study records for a minimum of two (2) years after the later of the following two dates: the date on which the study is terminated/completed or the date that the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a clinical product development protocol. The data for some of these records may be available in computerized form but the final responsibility for maintaining study records remains with the Investigator.

The Investigator may withdraw from the responsibility to maintain records for the period required by transferring custody of the records to any other person who will accept

	Title: Clinical Investigation Plan:	Page No: 24 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

responsibility for retaining them. Notice of a transfer shall be given to the Sponsor and FDA, if applicable, not later than ten (10) working days after the transfer occurs.

13.0 MONITORING PLAN

The Sponsor will designate trained and qualified personnel to monitor the progress of this study in accordance with established procedures and the study-specific Clinical Monitoring Plan.

Prior to study start, a Site Initiation Visit (SIV) will be conducted to review with the Investigator(s) and clinical site personnel the provisions and proper conduct of this study. This visit will include a detailed review of the study's CIP, verification that all necessary documents are on file at the clinical site and confirmation of IRB/EC approvals.

During the study, Interim Monitoring Visits (IMVs) will be conducted to assure the clinical site continues to adhere to the CIP, the investigator agreement, and regulations regarding conduct of clinical studies. The Monitor will confirm that the ICF to be used is the IRB/EC approved version, confirm the applicable national privacy laws have been followed, verify that all necessary documents are on file at the clinical site and confirm that there are provisions to continue and maintain all documents and records throughout the study as required by applicable regulations. These monitoring visits will assess, at a minimum, continued CIP compliance, adequate subject enrollment, accurate data reporting (that is, source data verification according to the Clinical Monitoring Plan), monitoring of subject safety through identification and/or review of any device-related AEs, U(S)ADEs, Serious Health Threats, DDs or SAEs, device accountability, continued maintenance and calibration of study-specific equipment (if applicable), and continued IRB/EC acceptance of the study.

At the completion of the study, the Sponsor-Monitor will conduct a final Close-Out Visit (COV). The purpose of this visit may include but is not limited to collecting all outstanding study data documents, confirming that the Investigator's files are accurate and complete, reviewing the record retention requirements with the Investigator, providing for the return of unused devices to the Sponsor, reviewing records which account for device shipments and ensuring that all applicable requirements for closure of the study are met.

14.0 AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

A CIP amendment is required when there is a change which will impact study conduct and/or subject safety, including changes of study objectives, study design, subject population, sample size, study procedures, or significant administrative aspects.

All amendments will be reviewed and approved by the Sponsor according to their procedures. Related documents, including but not limited to, ICF, IB, CRFs, and SAP will be reviewed and revised to align with the amended CIP, as required.

Amendments and affected related documents will be communicated to each Principal Investigator and clinical site as soon as possible and submissions made to their corresponding IRB/EC for review and approval. Amended CIPs will only be instituted at clinical sites after IRB/EC approval has been received.

15.0 DEVIATIONS FROM THE CLINICAL INVESTIGATION PLAN

	Title: Clinical Investigation Plan:	Page No: 25 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

A protocol deviation is defined as an event where the PI or clinical site personnel did not conduct the study according to the CIP, applicable regulations and standards, or requirements imposed by the IRB/EC.

A major protocol deviation is defined as an event where the participant's rights, safety and well-being, or the scientific integrity of the clinical investigation are affected. An observed example of a major PD in previously conducted urine output management investigations is failure to properly set-up or turn on the device resulting in no urine capture that could affect the objectivity of the primary efficacy.

CIP deviations are not permitted except when necessary to protect the life or physical well-being of a subject. The Sponsor and the clinical site's IRB/EC must be notified immediately if an emergency situation arises in which the safety of a subject may require immediate intervention different than that defined in the CIP. This must be followed by written confirmation that describes the emergency action and outcomes, within five (5) working days from the date of the emergency action in accordance with the governing IRB/EC's requirement.

It is the Principal Investigator's responsibility to ensure that there are no deviations from the CIP. Any and all deviations must be recorded on the appropriate CRF regardless of whether medically justifiable. Upon evaluation by the Sponsor, actions may be required to prevent additional deviations, such as retraining of the clinical site, implementation of additional clinical site procedures, and more frequent monitoring. If these steps fail, in accordance with Sponsor procedures, additional corrective and preventative actions may be taken, up to and including termination of enrollment at the clinical site and/or disqualification of the PI.

16.0 DEVICE ACCOUNTABILITY

Clinical products will be released only for use by Investigators who have obtained written IRB/EC approval (as required) for participation in this study, who have completed all required study documentation, and who have been qualified by the Sponsor. Investigators must maintain control over all clinical products, and ensure they are used in accordance with this CIP. Failure to do so may result in the Sponsor suspending or terminating the study at the Investigator's site.

The PI will ensure that clinical products are only dispensed to subjects properly enrolled in the study. The PI must maintain records of receipt, disposition, return and/or destruction of all clinical products. All clinical products released to the clinical site must be accounted for at the unit level prior to study close out, regardless of disposition. The Sponsor-Monitor will regularly review all records regarding clinical product accountability, in accordance with the study-specific Clinical Monitoring Plan.

The Sponsor will maintain records that document the shipment, receipt, disposition, return and/or destruction of clinical products.

17.0 STATEMENT OF COMPLIANCE

The study will not commence at a clinical site until approval from the respective IRB has been received. This study will be conducted in compliance with the following:

- The study's Clinical Investigation Plan,
- Any signed study agreements with the study Sponsor,
- Any IRB requirements,

	Title: Clinical Investigation Plan:	Page No: 26 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

- Food and Drug Administration (FDA) Code of Federal Regulations (CFR)
 - Title 21 Part 11 – Electronic Records, Electronic Signatures
 - Title 21 Part 50 – Protection of Human Subjects
 - Title 21 Part 54 – Financial Disclosure by Clinical Investigators
 - Title 21 Part 56 – Institutional Review Boards
 - Title 21 Part 812 – Investigational Device Exemptions
- International Organization for Standardization (ISO) 14155:2020 – Clinical Investigations of Medical Devices for Human Subjects – Good Clinical Practice,
- Ethical principles that have their origin in the Declaration of Helsinki.

18.0 INFORMED CONSENT PROCESS AND OTHER ETHICAL/REGULATORY CONSIDERATIONS

18.1 Informed Consent

Prior to any study procedure, the PI (or designee) must explain to each subject in layman's terms, the nature of the study, its purpose, expected duration, and the risks and benefits of study participation. Also, subjects will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them. All applicable national privacy laws (for example, HIPAA requirements in the U.S.) will be followed in this study. The subjects must be informed of their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which they are otherwise entitled, and that withdrawal from the study will not jeopardize their future medical care. Subjects will be informed of their right to new information and/or findings relating to the clinical study, and the process by which this information is made available. After this explanation, given sufficient time to decide whether to participate, before any study procedure is conducted, and before entering the study, the subject must voluntarily provide consent. The subject will receive a copy of their signed ICF. Failure to obtain informed consent prior to the conduct of any protocol-specific procedures should be reported to the Sponsor within five (5) days of site awareness.

In this study, legally authorized/designated representatives (LARs) may be used to provide consent if it is not possible to obtain consent from the subject. All of the information and requirements noted above apply to the process of obtaining consent from an LAR. The subject shall be asked to provide informed consent for continued participation as soon as their medical condition allows.

The ICF may be modified, with Sponsor approval, to suit the requirements of the individual clinical site.

18.2 IRB/EC Approval

Investigators or designees must submit the CIP, Informed Consent Form (if applicable), and all other locally required documentation to an appropriate IRB/EC and obtain study-specific written approval (favorable opinion) before being allowed to participate in the study. Before commencement of the study, the Investigator or designee must provide the Sponsor with written documentation of such approval. The IRB/EC must give written renewal of the original approval at least annually to continue the study. A copy of the written renewal must be provided to the Sponsor.

	Title: Clinical Investigation Plan:	Page No: 27 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

The IRB/EC will be notified of any amendments to the CIP, as well as possible associated information and consent form changes, where applicable, and written approval (favorable opinion) will be obtained prior to implementation, as applicable.

The Investigator or designee is responsible for fulfilling any conditions of approval imposed by the IRB/EC, such as regular safety reporting, study timing, etc. The Investigator or designee will provide the Sponsor with copies of such reports.

Upon study completion, a copy of the final IRB site close-out report should be provided to the Sponsor, if applicable. If the IRB withdraws approval of the study prior to completion, the Sponsor should be notified immediately, followed by a copy of the IRB notification within five (5) working days of withdrawal.

A list of IRB/EC names, locations, and chairpersons will be maintained under a separate cover.

18.3 Confidentiality

Subject confidentiality must be strictly held in trust by the PI, study staff, and the Sponsor. Subject confidentiality and anonymity will be maintained by removal of identifiers from any data, documentation, or clinical samples submitted to the Sponsor.

Any data collected meeting the definition of protected/confidential health information or personal identifying information will be collected and maintained using the designated authorizations and following privacy procedures as specified in the applicable health authority regulations.

The Sponsor-Monitor, authorized representatives of the sponsor, and/or applicable Health Authorities may inspect all documents and records required to be maintained by the Investigator. The Investigator/Clinical Site will permit access to such records.

19.0 ADVERSE EVENTS, ADVERSE DEVICE EFFECTS, AND DEVICE DEFICIENCIES

19.1 Definitions of Events

19.1.1 Adverse Events (AEs)

An AE is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. This definition includes events related to the investigational medical device or the comparator. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.

Pre-existing conditions should be considered as part of the subject's medical history and should not be reported as an AE unless there is a substantial increase in severity or frequency of the condition, which has not been attributed to natural history. Likewise, planned hospital visits and/or hospital stays (including planned re-interventions or procedures required by this study) should not be considered as adverse events. Exacerbation of an existing condition should be reported as an AE if the event meets the CIP definition of an AE.

19.1.2 Serious Adverse Events (SAEs)

	Title: Clinical Investigation Plan:	Page No: 28 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

A serious adverse event is defined as an adverse event that led to any of the following:

- a) Death,
- b) Serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:
 - 1) A life-threatening illness or injury,
 - 2) A permanent impairment of a body structure or a body function including chronic diseases,
 - 3) In-patient or prolonged hospitalization,
 - 4) Medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function.
- c) Fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment.

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

19.1.3 Adverse Device Effect (ADE)

An adverse device effect (ADE) is defined as an adverse event related to the use of an investigational medical device. This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device. This includes 'comparator' if the comparator is a medical device.

19.1.4 Serious Adverse Device Effect (SADE)

A SADE is defined as an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

19.1.5 Unanticipated (Serious) Adverse Device Effect (UADE/USADE)

An UADE/USADE is defined as a (serious) adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment. Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

19.1.6 Serious Health Threat

A serious health threat is defined as signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons. This would include events that are of significant and unexpected nature such that they become alarming as a

	Title: Clinical Investigation Plan:	Page No: 29 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

potential serious health hazard or possibility of multiple deaths occurring at short intervals.

19.1.7 Device Deficiency

A device deficiency is defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling. This definition includes device deficiencies related to the investigational medical device or the comparator.

This applies to: devices used to treat the subject, or devices in which the package was opened, but the device was not used for treatment, or devices with which treatment was attempted, but the device did not remain through the entire study procedure/period.

The Principal Investigator will record all device deficiencies for both the study device and the comparator, if the comparator is a medical device, on the appropriate CRF. Device deficiencies will be reported to the Sponsor.

If the device deficiency was associated with an AE, the reporting provisions for AEs, ADEs, SAEs, SADEs and UADEs/USADEs apply.

It is the responsibility of the Investigator to notify the IRB/EC of such device deficiencies in accordance with the IRB/EC and/or the Competent Authority's local regulations.

19.2 Severity of Adverse Events

Each AE shall be assessed for its severity, or the intensity of an event, experienced by the subject according to the criteria below.

Severity Rating	Description
Mild	Event, signs, or symptoms that do not interfere with the subject's daily activity, are usually considered self-limiting, can be treated with non-prescription type medications, and do not require medical intervention.
Moderate	Event may interfere or cause low level inconvenience with the subject's daily activity. Requires medical intervention and/or treatment; however, unlikely to require hospitalization or be considered potentially life-threatening in nature.
Severe	Event may cause significant discomfort to the subject and/or interferes with the subject's daily activity. Requires medical intervention and/or treatment to preclude a permanent impairment; may be life threatening and/or require hospitalization.

19.3 Relationship of Adverse Event to Device(s)/Procedure

Each AE will be assessed for its relationship to the study device or procedure according to the following guidelines.

Assess each AE for its relationship to the device or procedure.

	Title: Clinical Investigation Plan:	Page No: 30 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

- **Device Related:** This category should be restricted to AEs directly attributable to the study device used during the treatment period.
- **Procedure:** A procedure includes any study-related activity performed during the treatment period.

The following categories shall be used for assigning the certainty of the relatedness. An event is considered to be related if a relatedness category other than "Not Related" is assigned. See example table below.

Relatedness	Description
Not Related	Relationship to the device, comparator or procedures can be excluded when: - The event has no temporal relationship with the use of the investigational device, or the procedures related to application of the investigational device, - The AE/SAE does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible, - The discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the AE/SAE, - The event involves a body-site or an organ that cannot be affected by the device or procedure, - The AE/SAE can be attributed to another cause (for example, an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors), - The event does not depend on a false result given by the investigational device used for diagnosis, when applicable, In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.
Possible	The relationship with the use of the investigational device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (for example, an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible
Probable	The relationship with the use of the investigational device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.

	Title: Clinical Investigation Plan:	Page No: 31 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Relatedness	Description
Causal Relationship	The AE/SAE is associated with the investigational device, comparator or with procedures beyond reasonable doubt when: - The event is a known side effect of the clinical product category the device belongs to or of similar devices and procedures, - The event has a temporal relationship with investigational device use/application or procedures, - The event involves a body-site or organ that • the investigational device or procedures are applied to; • the investigational device or procedures have an effect on, - the AE/SAE follows a known response pattern to the medical device (if the response pattern is previously known), - The discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious adverse event (when clinically feasible), - Other possible causes (for example, an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out, - Harm to the subject is due to error in use, - The event depends on a false result given by the investigational device used for diagnosis, when applicable.

19.4 Reporting of Events

For all adverse events, all sections of the appropriate electronic Case Report Form (eCRF) must be completed including AE start and end date, outcome of AE, severity, seriousness, relationship to device and relationship to the procedure. All AEs shall be promptly reported to the Sponsor.

An event (for example, AE, SAE, DD) will not be considered reported to the Sponsor until the clinical site has entered the event into the study database.

19.4.1 Report by Investigator to Sponsor and IRB/EC

- All SAEs, SADEs, UADEs/USADEs, and Serious Health Threats must be reported to the Sponsor no later than 3 calendar days of the clinical site/investigator becoming aware of the event. If the study team is unable to access the electronic data capture system, the event may be reported to the Sponsor by emailing UCC.ClinicalSafety@bd.com, the Project Manager, Clinical Research Associate and Medical Monitor assigned to this study
- All AEs must be reported to the Sponsor no later than 3 calendar days.
- All device deficiencies must be report to the Sponsor no later than 3 calendar days.

	Title: Clinical Investigation Plan:	Page No: 32 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

- De-identified copies of all requested relevant documentation should be submitted to the Sponsor within 72 hours of the Sponsor's request.
- The Principal Investigator must report adverse events to individual Institutional Review Boards (IRBs)/Ethics Committees (ECs) per the IRB/EC requirements.

19.5 Safety Committees

19.5.1 Medical Monitor

An independent medical monitor will be responsible for safety oversight of this study. Detailed responsibilities can be found in the Clinical Safety Plan.

19.5.2 Clinical Events Committee

Not applicable.

19.5.3 Data Monitoring Committee

Not applicable.

20.0 SUSPENSION OR PREMATURE TERMINATION OF THE STUDY

The Sponsor reserves the right to suspend enrollment or terminate the study at any time for any reason. The Sponsor may suspend enrollment or terminate the study at a specific clinical site for reasons including, but not limited to, inadequate data collection, low subject enrollment rate, achievement of the total enrollment, conditions imposed by the reviewing IRB/EC and/or non-compliance with this Clinical Investigation Plan or other clinical research requirements. Written notice will be submitted to the Investigator in advance of such termination.

In the event of study suspension or termination, the Sponsor will send a report outlining the circumstances to the IRB, and all Investigators and regulatory authorities as required by regulation.

In the event of suspension or study termination, the Sponsor will remain responsible for providing resources to fulfill the obligations set forth in the protocol and CSA to allow for treated subjects to be followed through the <insert final follow-up visit> study follow-up period.

The Sponsor may consider suspending or terminating an investigational site or the study for reasons including, but not limited to, unacceptable safety risk to subjects, inadequate data collection, low subject enrollment rate, achievement of the total enrollment, conditions imposed by the reviewing IRB/EC and/or non-compliance with this protocol or other clinical research requirements. If suspicion of an unacceptable risk to subjects arises during the study, or when so instructed by the IRB/EC or regulatory authorities, the Sponsor shall suspend the study while the risk is assessed. The Sponsor shall then terminate the site or study if an unacceptable risk to subjects is confirmed and cannot be addressed.

If, for any reason, the Sponsor suspends or terminates the study at an investigational site, the Sponsor shall inform the responsible regulatory authority as appropriate and ensure that the IRB/EC is notified, either by the Principal Investigator or the Sponsor. The Principal Investigator (or designee) will also be responsible for promptly informing the enrolled subjects at their investigational site, if appropriate. If a site suspension or termination was in the interest of safety, the Sponsor will inform all other Principal Investigators. The Investigator must also notify the IRB/EC in writing as soon as possible but no later than within ten (10) working days if a suspension or termination is related to safety or compliance issues.

	Title: Clinical Investigation Plan:	Page No: 33 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

In the event of a temporary site or study suspension, the Sponsor should conduct an analysis of the reason(s) for the suspension and implement any necessary corrective actions. If the Sponsor decides to lift a temporary site or study suspension, the Sponsor will inform the Principal Investigators and IRB/ECs, where appropriate, of the rationale and provide them with the relevant data supporting this decision. The study may not be reinitiated without concurrence and approval from the reviewing IRB/ECs and/or regulatory authorities, as required by regulation.

21.0 PUBLICATION POLICY

The Sponsor believes that results of applicable clinical studies should be published in peer-reviewed literature in a timely, accurate, complete, and balanced manner, regardless of study outcomes, whenever possible. As such, at the conclusion of this study, an article may be prepared for publication in a reputable scientific journal. Formal presentation(s) or publication(s) of data collected from this study will be considered as a joint publication by the investigator(s) and the appropriate personnel of the Sponsor. Authorship will be based on generally accepted criteria of the ICMJE (International Committee of Medical Journal Editors) and determined by mutual agreement.

The publication of the principal results from any single-center experience within the study is not allowed until the preparation and publication of the multicenter results. Exceptions to this rule require the prior approval of the Sponsor. The analysis of other pre-specified and non-pre-specified endpoints will be performed by the Sponsor or its designee. Such analyses, as well as other proposed studies or manuscripts will require the approval of the Sponsor.

22.0 STUDY REGISTRATION

In compliance with Title VIII of Public Law 110-85, known as FDA Amendments Act of 2007 (FDAAA) and/or national regulations, the Sponsor will register this study and disclose study results in a publicly accessible database (for example, ClinicalTrials.gov;). This study will be registered prior to first subject enrollment or no later than 21 days after commencing enrollment. Study results will be posted website within 12 months [of the last subject visit for collection of primary outcome data] or after health authority approval.

23.0 ADMINISTRATIVE REQUIREMENTS

23.1 Audits and Inspections

If the study is selected for audit by the Sponsor or if there is an inspection by the appropriate Health Authorities, the Investigator and their team will make themselves available during the visit. The Investigator must agree to the inspection of all study related records and give the auditor/inspector direct access to source documents for verification of data on CRFs. The subject's anonymity must be ensured, and data checked during the audit must remain confidential.

As soon as the PI is aware of an upcoming inspection/audit by the Health Authorities, they will promptly inform the Sponsor. As agreed with the PI, Sponsor personnel may be present at the clinical site during the inspection.

23.2 Investigator and Clinical Site Selection

	Title: Clinical Investigation Plan:	Page No: 34 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

Investigators must be of good standing and knowledgeable in relevant areas of clinical research to ensure adherence to the requirements of this CIP, including the protection of human subjects. Other clinical site personnel must have appropriate research experience and infrastructure to ensure adherence to this CIP and enrollment of sufficient numbers of evaluable subjects. The curriculum vitae (CV) of the PI(s) and Sub-Investigator(s) will be maintained in the Sponsor's files as documentation of qualification by training and experience.

Government databases will be searched to ensure that the Investigator(s) and/or the site are not prohibited from engaging in clinical research.

Any clinical site that is deactivated prior to initial enrollment, either by the Sponsor or by the individual clinical site itself, may be replaced.

23.3 Training

In addition to each Principal Investigator and appropriate clinical site personnel being trained on this CIP and its procedures during the Site Initiation Visit, clinical product training will be provided by the Sponsor or designee and is required for each PI. Additional study personnel (for example, Sub-Investigator(s)) will also require device training provided from the Sponsor or proctoring by the PI. All training will be documented and filed at the clinical site and with the Sponsor.

23.4 Required Documents

An Investigator may not screen or enroll subjects until authorized to do so by the Sponsor. At a minimum, the Sponsor should have the following documentation prior to commencement of study activities:

- Fully executed Confidentiality Disclosure Agreement,
- Fully executed clinical contract,
- Investigator(s) signed CIP signature page,
- Signed Investigator Agreement(s),
- Signed Financial Disclosure Form(s),
- CVs, current, signed, and dated for all clinical site personnel,
- Debarment screening acceptable,
- Delegation of Authority is complete and signed,
- Study-specific Clinical Site Training Log is complete and signed for applicable clinical site personnel,
- IRB/EC approval of CIP, ICF and other applicable subject facing material,
- IRB roster/EC membership list.

23.5 Regulatory Status

The PureWick™ System, comprised of the PureWick™ Male External Catheter and the PureWick™ Urine Collection System, is a Class I, 510(k) exempt device currently marketed in the United States and will be evaluated for its approved indication.

This is a post-market study collecting data on currently marketed devices. Institutional Review Board (IRB) or Ethics Committee (EC) submission of this study plan along with

	Title: Clinical Investigation Plan:	Page No: 35 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

IRB/EC study approval or waiver is required. The study will comply with the abbreviated IDE requirements under CFR 812.2 (b).

The Sponsor has determined and documented this to be a non-significant risk device study based on congruency with 21 CFR 812.3. This determination is based on the following assessment of the study device:

- Is not intended as an implant,
- Is not purported or represented to be for a use in supporting or sustaining human life,
- Is not intended for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health,
- Does not present a potential for serious risk to the health, safety, or welfare of a subject.
- Classification of NSR is documented in the Study Risk Assessment Form.

24.0 REFERENCES

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6. Brown JS, Vittinghoff E, Wyman JF, et al. Urinary incontinence: Does it increase risk for falls and fractures? Study of Osteoporotic Fractures Research Group. *J Am Geriatr Soc*. 2000;48(7):721-725.
7. Thom DH, Haan MN, Van Den Eeden SK. Medically recognized urinary incontinence and risks of hospitalization, nursing home admission and mortality. *Age Ageing*. 1997;26(5):367-374.

25.0 VERSION HISTORY

Ver. #	Date (DD-MMM-YYYY)	Change Owner	Description and Justification of Change
1.0	18-DEC-2024	Ajesh Raju	Original

Include only the three (3) most recent revisions.

	Title: Clinical Investigation Plan:	Page No: 36 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

26.0 APPENDICES

26.1 Appendix 1 – PureWick™ Male External Catheter IFU PWMX30

Refer to supporting documents in the Trial Master File.

26.2 Appendix 2 – PureWick™ Urine Collection System IFU PW100 & PW200

Refer to supporting documents in the Trial Master File.

26.3 Appendix 3 – UltraFlex™ Self-Adhering Male External Catheter IFU 33102, 33302

Refer to supporting documents in the Trial Master File.

26.4 Appendix 4 -- End of Study Preference Questionnaire (Sample)

Participant Number:	
Thank you for participating in this study. Now that you have experienced the use of two urine collection devices, please answer a few questions about your experiences with the devices. As a reminder, during the study, you used two devices overnight while sleeping: During the first part of the study, you used the <i>PureWick™ Urine Collection System/ UltraFlex™ Self-Adhering Male External Catheter</i> During the second part of the study, you used the <i>PureWick™ Urine Collection System/ UltraFlex™ Self-Adhering Male External Catheter</i>	
1. Do you remember using each of these devices? _____ Yes _____ No <If No or if there is significant difficulty in differentiating the 2 study phases, discontinue the interview.> 2. Which device did you prefer? _____ PureWick™ Urine Collection System _____ UltraFlex™ Self-Adhering Male External Catheter 3. What made you choose the <PureWick/UltraFlex> device? Why did you prefer that device?	

	Title: Clinical Investigation Plan:	Page No: 37 of 37
	Study ID: UCC-24HC013	Version No: 1.0

Template GFM-10095B

<Ask follow-up questions, as much as practical, to better understand the participant's preference>

26.5 Appendix 5 – PROMIS Sleep Disturbance Short-form 4

Refer to supporting documents in the Trial Master File.

Signature Page for VV-TMF-330578 v1.0

Reason for signing: Finalize	Name: Ajesh Raju Role: Clinical Project Management Date of signature: 02-Jan-2025 18:29:51 GMT+0000
Reason for signing: Finalize	Name: Srini Gopal Role: Clinical Data Manager Date of signature: 02-Jan-2025 19:06:40 GMT+0000
Reason for signing: Finalize	Name: Shuangshuang Fu Role: Clinical Statistician Date of signature: 02-Jan-2025 19:19:42 GMT+0000
Reason for signing: Finalize	Name: Danielle Redmond Role: Medical Affairs Core Team Member Date of signature: 02-Jan-2025 19:22:15 GMT+0000
Reason for signing: Finalize	Name: Bhawankumar Patel Role: Clinical Quality and Compliance Date of signature: 02-Jan-2025 20:32:44 GMT+0000
Reason for signing: Finalize	Name: Kirsten Hammitt Role: Site Management and Monitoring and Clinical Safety Management Date of signature: 02-Jan-2025 20:53:52 GMT+0000
Reason for signing: Finalize	Name: Amy Lewis Role: Legal Date of signature: 03-Jan-2025 14:00:41 GMT+0000
Reason for signing: Finalize	Name: Christy Zeigler Role: Clinical Data Manager Date of signature: 03-Jan-2025 15:11:02 GMT+0000

Signature Page for VV-TMF-330578 v1.0