BD	**Document Type**: Global Clinical	
	Title: Clinical Investigation Plan **Study ID:** UCC-23AC023	Version No: **1.0**

Template GFM-10095B

Clinical Investigation Plan	
Study Title	A prospective, uncontrolled, open-label healthy volunteer study to assess the performance of the PureWick™ Male and PureWick™ Flex Female external catheter devices in adolescents (PureWick Adolescent Study)
Study ID	UCC-23AC023
CIP Version and Date	V1.0 / August 9, 2024
Registration Number(s)	ClinicalTrials.gov
Study Device	PureWick™ Flex Female External Catheter (PWFXH30) PureWick™ Male External Catheter (PWMX30) PureWick™ Urine Collection System (PW100)
Sponsor Name	Becton, Dickinson and Company 8195 Industrial Blvd. Covington, GA 30014
Sponsor Contact	Ajesh Raju Clinical Project Manager Ajesh.Raju@bd.com
Principal Investigator	Jesson Yeh, M.D Principal Investigator TKL Research Inc. One Promenade Boulevard Suite 1101/1201 Fair Lawn, NJ 07410
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.

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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/YYY):
Clinical Site Name		

BD	**Document Type**: Global Clinical	
	Title: Clinical Investigation Plan **Study ID:** UCC-23AC023	Version No: **1.0**

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1.0 SYNOPSIS

Registration	Clinicaltrials.gov	
Study Device	PureWick™ Flex Female External Catheter (PWFXH30) PureWick™ Male External Catheter (PWMX30) PureWick™ Urine Collection System (PW100)	
Stage of Development	Post-market expanded use	
Background and Rationale	The purpose of this study is to evaluate the performance and intended use of PureWick™ Male External Catheter and PureWick™ Flex Female External Catheter in the adolescent patient population.	
Objectives and Endpoints	Objective(s)	Endpoint(s)
	Primary • To assess the performance of the PureWick™ Flex FEC and PureWick™ MEC in adolescents after HCP placement and participant (or guardian/parent) placement	Primary • Capture rate following void (captured as % of urine captured by device and collected in canister measured by weight) • Perception of wetness following each void on a 5-point Likert scale (brief questionnaire)
	Secondary • To assess ease of use by HCP and participant • To assess participant comfort after using the PureWick™ Flex FEC and PureWick™ MEC • To evaluate the Instructions for Use in the adolescent population for PureWick™ Male External Catheter and PureWick™ Flex Female External Catheter	Secondary • Ease of use score on a 5-point Likert scale (brief questionnaire) • Overall comfort score on a 5-point Likert scale (brief questionnaire) • IFU comprehension score on a 5-point Likert scale (brief questionnaire)
Study Design	This is a prospective, uncontrolled, open-label, randomized healthy volunteer study to assess the performance of the PureWick™ Male External Catheter and the PureWick™ Flex Female External Catheter in adolescents following a void with HCP placement of the device and a void with participant (or guardian/parent) placement of the device.	
Number of Subjects	40 participants (20 male and 20 female)	
Subject Population	Adolescents aged 12 through 21 (up to but not including the 22nd birthday), Healthy Volunteers. This study will need to enroll, at a minimum, one male participant and one female participant 12 years of age, and one male participant and one female participant 21 years of age. Additionally, the study will aim to enroll 50% of the population in the 12-17 year age range and 50% of the population in the 18-21 year age range.	

Subject Inclusion/Exclusion Criteria	Inclusion Criteria: 1. Healthy Adolescent Male or Female aged 12 through 21 years old 2. Able to independently and voluntarily void urine 3. Ability to speak and understand English. 4. Willing to comply with all study procedures in the protocol. 5. Provision of signed and dated informed consent form. Exclusion Criteria: 1. Has urinary retention 2. Incontinent to feces 3. Has any irritation, wound, open lesion at the device application site. 4. For females: currently menstruating without use of an internal device, e.g. tampon or menstrual cup, during the execution of the study. 5. For females: currently pregnant at time of consenting (self-reported) 6. Currently enrolled in or has previously been enrolled in or has completed nursing or other clinical training and courses. 7. Has ever been employed as a home health aide or homecare provider. 8. Any other condition that, in the opinion of the investigator, would preclude them from participating in the study.
Interventions / Measurements / Procedures	Participants will evaluate the PureWick™ Male External Catheter (for males) or the PureWick™ Flex Female External Catheter (for females). Both devices are intended for non-invasive urine output management and utilize suction to pull voided urine away from the body through tubing into a collection canister. For each device evaluation, participants will have the device placed by a healthcare professional (HCP) for one void and will self-place the device for the other void. With the device in place, participants will urinate two separate times in this study to evaluate the performance of the device in the adolescent population. After each void, the device will be removed by the HCP or self-removed. Finally, the participants will be asked to complete brief questionnaires to assess comfort, ease of use, ability to assemble device and IFU comprehension. HCPs will also be asked to complete questions about ease of use for the voids in which they place and remove the device.
Duration of Study Participation	Expected participation time is approximately 2-3 hours, divided across two voids. Prior to the first void, each participant will be consented and trained on device instructions for use.
Clinical Sites	1 US site
Study Timeline	Planned Enrollment Start: Approximately August 30, 2024
Data Monitoring Committee	N/A - DMC not required for the study
Clinical Events Committee	N/A - CEC not required for this study
Regulatory Status	Non-significant risk IDE. Study will evaluate legally marketed products in a new population for expanded indication.

2.0 ABBREVIATIONS

Abbreviations	Term
AE	Adverse Event
ADE	Adverse Device Effect
AFMEA	Application Failure mode and Effects Analysis
ASADE	Anticipated Serious Adverse Device Effect

Abbreviations	Term
BD	Becton, Dickinson and Company
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
EDC	Electronic Data Capture
FEC	Female External Catheter
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act of 2007
GCP	Good Clinical Practice
HCP	Healthcare Professional
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonization
IFU	Instructions for Use
IRB/EC	Institutional or Independent Review Board/Ethics Committee
ISO	International Organization for Standardization
MEC	Male External Catheter
PI	Principal Investigator
PUCS	PureWick™ Urine Collection System
PW	PureWick™
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SD	Standard Deviation
TMF	Trial Master File
USADE	Unanticipated Serious Adverse Device Effect

3.0 STUDY SCHEDULE

Visit	Study Activity	Activity
Visit 1	Obtain Consent	Obtain consent for study participants. For minor participants, consent will be obtained from the participant's parent or guardian and assent provided by the minor participant.
	Screening & Randomization	Screen potential participants against the inclusion and exclusion criteria. Randomly assign participants to placement sequence
	Baseline	Collect participant demographic data including height and weight. HCP completes a visual assessment of the skin in the device application area.
	Device use and urine measurement collection	After enrollment and randomization, train the participant to the device IFU. Prior to device placement, HCP assembles and sets up the PUCS. The study device will then be placed by the HCP, participant (or guardian/parent) per the assigned placement sequence. Placement will be confirmed by the HCP and then participant will void. Post-void, the device will be removed by the HCP, participant (or guardian/parent) and bed pad and canister weights will be captured. Above steps will be repeated for void 2.
	Questionnaires	Participants complete the questionnaires below. • Perception of wetness • Ease of use • Comfort • IFU Evaluation After completion of all participants, each HCP completes this questionnaire once per device.
	Participant Completion	Participants will be discharged from the study after completing all study activities.
	Study Completion	End of study is when the last study participant is discharged.

4.0 INTRODUCTION

4.1 Background

Urinary incontinence increases the risk for complications such as incontinence-associated dermatitis (IAD) and pressure ulcers[1-4], and treatment can be difficult, time-consuming, and costly[4]. Prolonged usage of an indwelling Foley catheter is a well-known risk factor for the development of catheter-associated urinary tract infections (CAUTI). The consequences of urinary tract infections (UTIs) can be serious as they have been found to increase mortality[5,6], prolong hospitalization, and increase readmissions[5]. UTIs are a leading cause of the development of bloodstream infections (BSIs) and sepsis, and the most severe infections are associated with increased morbidity, mortality, and costs.[6]

As a result, hospitals are going to great lengths to limit indwelling catheter utilization and minimize the duration of catheterization when it must be used. However, managing urine output without an indwelling catheter has been challenging given the limited device options recently available.

For male patients, condom catheters are an option for external drainage that may allow for accurate urine output measurements and/or management of urinary incontinence. However, there are several disadvantages and challenges associated with sheath-style condom catheter types of devices. First, appropriate sizing of condom catheters may be difficult; too large catheters may simply slip off the penis while too small catheters may cause pressure-associated tissue trauma.[7] Second, adhesives used to hold the catheter sheath in place may fail; too little adhesion causes sheath slippage while too strong adhesion may lead to skin damage when the sheath is removed.[7] Female patients, until recently, did not have widely available alternative options outside of traditional indwelling urinary catheters or diapers.

Incontinence in adolescents is a neglected research topic in both acute care and home settings. The literature reports prevalence rates of 2.55- 5.41 per 1000 catheter days in the acute care setting [9-12] and 1.35 per 1000 catheter days in the ambulatory setting. There is an abundance of literature available on IAD in adult and infant populations; pediatric populations are a high-risk group for IAD, with diaper dermatitis accounting for 20% of pediatric dermatology visits, IAD specifically is the most common presentation. However, no manuscripts could be found specifically addressing the adolescent prevalence of IAD, and there is limited consensus regarding the prevention of pediatric patients with IAD. In the adolescent population, incontinence management can be challenging and unreliable; additional urine management solutions are needed to address the skin and infection problems associated with urinary incontinence. In addition to the clinical outcomes, urinary management may impact the quality of life in adolescent patients and their caregivers. For example, one study found that children with spina bifida experience incontinence as distressing and unpredictable.[8]

The PureWick™ Urine Collection System (PUCS) is to be used with PureWick™ Flex Female External Catheters (FEC) or the PureWick™ Male External Catheter (MEC) which are intended for non-invasive urine output management and will be collectively referenced as the PureWick™ System throughout this study.

4.2 Rationale

The purpose of this study is to understand if external catheters are an effective alternative in the adolescent population in both male and female adolescents in the setting where the external catheter is placed by a healthcare professional as well as in the outpatient or home setting where the external catheter is self-placed or placed by guardian/parent, and to provide data to support potential labeling for an expanded population use. Specifically, the study will collect data about how the external catheters perform in terms of capture rate when participants are voiding after self-placement of the device, if the adolescent participant can use the device independently or with the help of a guardian/parent and collect any adverse events that are reported.

5.0 IDENTIFICATION AND DESCRIPTION OF THE STUDY DEVICE

5.1 Study Device(s) and Comparator(s)

Study participants will be evaluating the PureWick™ Male External Catheter (male participants) or the PureWick™ Flex Female External Catheter (female participants). Both study devices will be used with the PureWick™ Urine Collection System, a 510(k) exempt device currently marketed in the United States. All study devices will have a lot number for product traceability.

PureWick™ Male External Catheter

The PureWick™ Male External Catheter (Figure 1) 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. Male participants will void two times using the PureWick™ MEC. The study will utilize approximately 40 PureWick™ MECs, 2 per male participant.

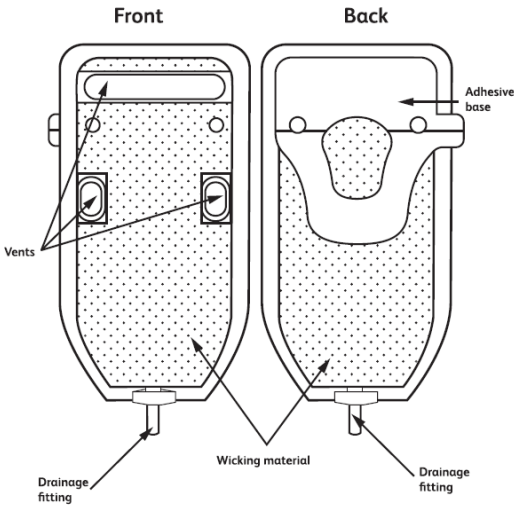

Figure 1

PureWick™ Flex Female External Catheter

The PureWick™ Flex Female External Catheter is intended for non-invasive urine output management in adult users with female anatomy. The PureWick™ Flex FEC (Figure 2) is a non-sterile single use device. The device is a flexible, contoured external catheter (a "Wick") that is positioned between the separated gluteus and labia, against the urethra. The wick is connected to the free-standing PureWick™ Urine Collection System (PUCS) via tubing. The PUCS uses suction (not felt by the user) to pull voided urine through the wick, regardless of the urine flow rate. Urine continues quickly through PVC tubing, away from the body until it reaches the collection canister.

The PureWick™ Flex FEC is currently on the market. The device is composed of silicone, polyester non-woven foam, bamboo mid-layer sheet, polypropylene top sheet, PVC dual lumen tubing; all materials common in medical devices. The device also consists of an aluminum wire inside of the dual lumen PVC tubing that allows the FEC to hold its shape when formed.

The device Instructions for Use (IFU) can be found in Appendix 2. Female participants will void two times using the PureWick™ Flex FEC. The study will utilize approximately 40 PureWick™ Flex FECs, 2 per female participant.

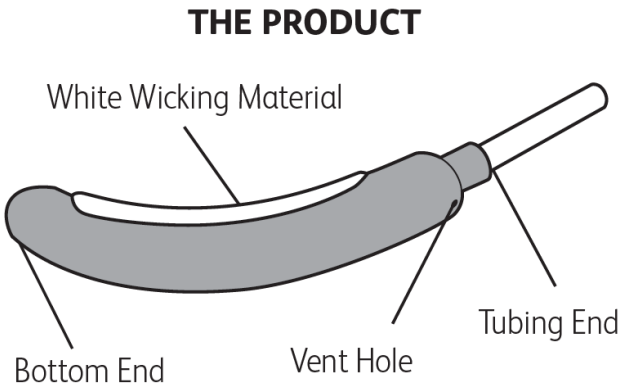

Figure 2

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

The PureWick™ Urine Collection System (PUCS) (Figure 3) is to be used with PureWick™

Male External Catheters and PureWick™ Flex FEC which are intended for non-invasive urine output management. The device 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). The system may be used in both home environments and professional care facilities. In this study, the device will be used according to the current IFU (Appendix 3).

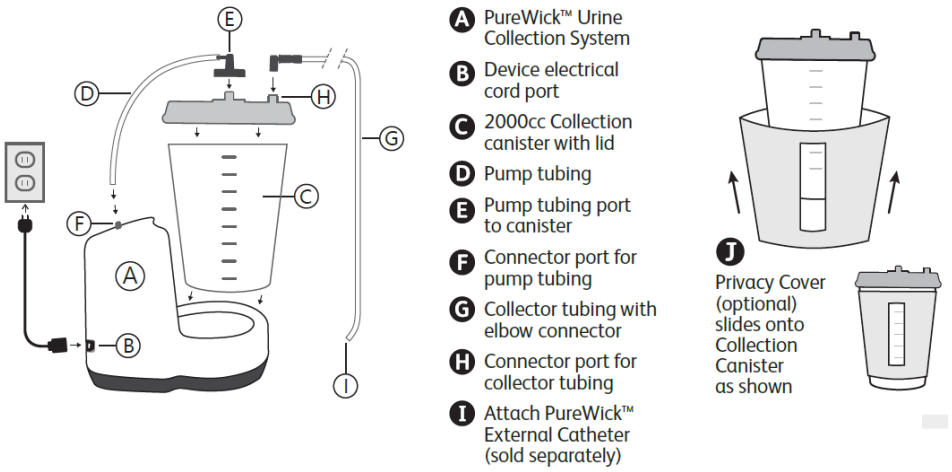

Figure 3

6.0 OBJECTIVES AND HYPOTHESES

6.1 Objectives and Endpoints

Objective Type	Objective	Endpoint
Primary	• To assess the performance of the PureWick™ Flex FEC and PureWick™ MEC in adolescents after HCP placement and participant (or guardian/parent) placement	• Capture rate following void (captured as % of urine captured by device and collected in canister measured by weight) • Perception of wetness following each void on a 5-point Likert scale (brief questionnaire)
Secondary	• To assess ease of use by HCP and participant • To assess participant comfort after using the PureWick™ FEC or PureWick™ MEC	• Ease of use score on a 5-point Likert scale (brief questionnaire) • Overall comfort score on a 5-point Likert scale (brief questionnaire)

	• To evaluate the Instructions for Use in the adolescent population	• IFU comprehension score on a 5-point Likert scale (brief questionnaire)

6.2 Performance Goal

Not applicable.

7.0 DESIGN OF THE STUDY

7.1 Overall Design

This prospective, uncontrolled, open-label, single-center, healthy volunteer study will assess the performance of the PureWick™ System in adolescents following a void with HCP placement of the device and a void with participant (or guardian/parent) placement of the device. Male participants will evaluate the PureWick™ Male External Catheter and female participants will evaluate the PureWick™ Flex Female External Catheter.

The expected participation time is approximately 2-3 hours, divided across two voids. Prior to the first void, each participant will be consented and trained on device instructions for use.

For each device evaluation, participants will have the device placed by a healthcare professional (HCP) for one void and will self-place the device for the other void. The participant may have a guardian or parent place the device only if the participants is unable or unwilling to self-place the device. With the device in place, participants will urinate two separate times during the study to evaluate the performance of the device in the adolescent population. After each void, the device will be removed by the HCP or self-removed (a guardian or parent may remove the device if the participant is unable or unwilling to remove the device). Finally, the participants will be asked to complete brief questionnaires to assess perceived wetness, IFU comprehension, comfort and ease of use. HCPs will also be asked to complete questions about ease of use for the voids in which they placed and removed the device.

Approximately 40 healthy participants (20 male and 20 female) will be enrolled into the study. The study will be conducted at one clinical site.

7.2 Justification for the Study Design

This non-significant risk IDE study will evaluate device safety and performance in the adolescent population. Evidence generated from this study will be used to support indication expansion.

7.3 Treatment Allocation and Measures to Minimize Bias

This is an open-label study in which participants will be randomized to a device placement sequence. All male participants will evaluate the PureWick™ Male External Catheter and all female participants will evaluate the PureWick™ Flex Female External Catheter. Standardized questionnaires and data collection tools will be used to assess capture performance, safety, participant comfort and ease of use.

7.3.1 Randomization

Participants will be randomized 1:1 to one of two placement sequences. A randomization list will be provided by the sponsor.

7.3.2 Blinding/Masking

Not applicable. This is an open label study.

7.3.2.1 Procedures for Unblinding

Not applicable – This is an open label study

7.4 Potential Influencing or Confounding Factors and Bias

This is an open-label, healthy volunteer study where participants will be randomized to a device placement sequence. All male participants will evaluate the PureWick™ Male External Catheter and all female participants will evaluate the PureWick™ Flex Female External Catheter. As such, no confounding factors are anticipated.

7.5 End of Study Definition

A subject is considered to have completed the study if they have completed all study procedures shown in Section 10.0.

The end of the study is defined as the date of the last visit of the last participant in the study.

7.6 Clinical Sites

This study will have one site, TKL Research Inc., located in Fair Lawn, NJ.

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

Participants in this study will be treated with either PureWick™ Male External Catheter or the PureWick™ Flex Female External Catheter which are Class I Exempt devices that will be used as intended. Therefore, participants will be exposed to the same risks shared by all patients using these devices.

Application failure mode and effects analysis (AFMEA) documents (PureWick™ Flex FEC RA0301999, PureWick™ MEC RA0301920 and PUCS RA0301678) were generated to summarize the risk analysis process and provide documented evidence that the risks associated with the study device are acceptable. Prior to study participation, the Investigator must explain to each subject the risks and benefits of this clinical study.

More detailed information about the known and expected benefits and risks and reasonably expected adverse events/adverse device effects of the PureWick™ Male External Catheter and PureWick™ Flex Female External Catheter may be found in the IFU for each device product.

8.1 Benefit Assessment

This is a healthy volunteer study in which the participants are not known to suffer from any of the conditions/indications for use of the PureWickTM Male External Catheter or PureWickTM Flex Female External Catheter. As such, there is likely to be no direct benefit for study participants. Data gathered through this study could benefit future patients utilizing the study devices. Study participants may contribute to the process of generating clinical evidence for urine output management in male and female adolescent patients.

8.2 Risk Assessment

8.2.1 Anticipated Adverse Device Effects

Potential Risk of Clinical Significance	Summary of Data/Rational for Risk	Mitigation Strategy
PureWick™ Flex Female External Catheter		
• Skin Injury • Skin Irritation • Allergic reaction • Inflammation • Infection • Discomfort	The PureWick™ Flex is a flexible, contoured external catheter (a "Wick" that is positioned between the separated gluteus and labia, against the urethra.	• To avoid potential skin injury, never push or rub the product against the skin during placement or removal. • Assess local area before application/after device removal and periodically throughout use. • Participants are allowed to discontinue use if they feel any pain or discomfort. • IFU (warning, contraindications, instructions) • Study Exclusion criteria
• Tissue injury or possible minor bleeding	The device sites against the skin, sticking and possible minor bleeding is a potential risk.	• Top layer of wicking material has been selected to minimize the possibility of sticking to skin.
• Exposure to Biohazard or bloodborne pathogens	Device is intended to capture urine, may lead to transmission of bloodborne pathogens.	• HCP will wear gloves when handling devices and will dispose of used devices per the IFU
• Injuries	Device is labeled MRI conditional. Potential interference with other medical devices or treatments under specific operating conditions.	• IFU (warnings) • No MRI included in the study procedures.
PureWick™ Male External Catheter		
• Skin injury • Skin Irritation • Allergic reaction • Infection • Discomfort	• 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. • Assess the device placement and patient's skin at least every 2 hours.

		• Monitor for pulling and tension on the device after turning the patient. • Replace the device every 24 hours or if soiled with feces, blood, or semen. • Remove the device prior to ambulation.
• Exposure to biohazard or blood borne pathogens	• Device is intended to capture urine, may lead to transmission of bloodborne pathogens.	• HCP 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.	• HCP will wear gloves when handling devices and will dispose of used devices per the IFU

8.2.2 Anticipated Procedure-related Adverse Events

Potential Risk of Clinical Significance	Summary of Data/Rational for Risk	Mitigation Strategy
• Potential discomfort due to full bladder.	• Participants will be asked to drink fluids in between voids to ensure a full second void.	• Participants who meet the eligibility criteria and follow study instructions should not have a bladder that is uncomfortably full.
• Potential biohazard exposure after use	• Device is intended to capture urine, may lead to transmission of bloodborne pathogens.	• Participants will be provided gowns and offered gloves during study participation

8.2.3 Additional Risks Associated with Study Participation

No additional risks associated with participation in this study have been identified.

8.3 Risk / Benefit Analysis

Taking into consideration the measures to minimize risk to subjects in this study, the potential risks identified in association with PureWick™ Male External Catheter and PureWick™ Flex Female External Catheter are justified by the anticipated benefits that may be afforded to subjects with requiring a non-invasive urine output management solution.

9.0 SUBJECTS

Adolescent male and female healthy participants will be recruited by the clinical site, TKL Research Inc. Participants will be recruited from the site's existing pool of volunteers in a database owned by the study site and with advertisements. It is anticipated to have 20 enrolled male and 20 enrolled female healthy volunteers aged 12-21 years old, with a target of 50% between 12-17 and 50% between 18-21. At least one male participant and one female participant must be the minimum age of 12, and at least one male participant and one female participant must be the maximum age of 21 to ensure representativeness across the target age range.

9.1 Inclusion Criteria

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

1. Healthy Adolescent Male or Female aged 12 through 21 years old
2. Able to independently and voluntarily void urine
3. Ability to speak and understand English
4. Willing to comply with all study procedures in the protocol
5. 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:

1. Has urinary retention
2. Incontinent to feces
3. Has any irritation, wound, open lesion at the device application site
4. For females: currently menstruating without use of an internal device, e.g. tampon or menstrual cup, during the execution of the study
5. For females: currently pregnant at time of consenting (self-reported)
6. Currently enrolled in or has previously been enrolled in or has completed nursing or other clinical training and courses
7. Has ever been employed as a home health aide or homecare provider
8. Any other condition that, in the opinion of the investigator, would preclude them from participating in the study.

9.3 Vulnerable Subjects

Human subject regulations consider pediatric subjects a vulnerable population. This study will require IRB review and approval prior to the start of the study. Prior to approval, the IRB must determine that no greater than minimal risk to children is presented in the study. Written informed consent using the IRB approved consent form will be obtained from all subjects or their parent/guardian prior to participating in the study. The IRB will determine if assent of the adolescent participants is required in addition to parent/guardian consent. No medical care will be provided to the study participants once the study has been completed.

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 Treatment

Once the participant meets all the eligibility criteria and signs the ICF, the participant is considered enrolled and study activities will begin as outlined in section 10.

9.4.2 Point of Randomization

Randomization assignment should occur only when all eligibility criteria are met and consent has been obtained. The point of randomization is after enrollment when the site assigns a subject to a device placement order per the Sponsor provided randomization list.

9.5 Screen Failures and Replacement of Subjects

Screen failures are defined as subjects who consent to participate in the clinical study but are not subsequently randomized into the study. Demographic information may be captured for screen failures. Screen failures will not be allowed to re-screen.

The Principal 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.

9.5.1 Replacement of Subjects

Not Applicable – This study will not have replacement participants.

9.6 Study / Participation Duration

9.6.1 It is expected to take approximately 2-3 weeks to complete subject enrollment. The total duration of the study is expected to be 2-3 weeks (last subject, last visit).

9.6.2 The duration of study participation for an individual subject is expected to be approximately 2-3 hours (enrollment through last study assessment).

9.7 Subject Discontinuation / Withdrawal [and Discontinuation of Intervention]

9.7.1 Discontinuation / Withdrawal

9.7.1.1 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.

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

9.7.1.3 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.

9.7.1.4 If a subject withdraws from the study, they may request destruction of any samples taken and not tested, and the Principal Investigator must document this in the clinical site study records.

9.7.1.5 Once the study has ended, there will be no additional care for study participants.

9.7.1.6 There will be no additional procedures/parameters in the study.

9.7.2 Lost to Follow-Up

The study only has one visit with two voids. There are no follow-up visits.

10.0 PROCEDURES

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 participants meet all eligibility criteria. The 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.

10.1 Screening and Enrollment Procedures

All participants will be screened against the inclusion and exclusion criteria (see section 9.1 & 9.2). Participants who fail to meet eligibility criteria must not have a study device placed.

The Investigator or their designee will explain the study to the participant, answer all of the participant's questions, and obtain written informed consent (and assent, as applicable) before the collection of any study data or performance of any study procedures.

10.2 Medical History / Baseline Assessments

Participants demographic information including age, race, ethnicity, sex, height, and weight (for BMI calculation) will be collected at baseline.

10.3 Randomization

The site will receive a randomization list of placement sequence numbers. Participants can only be randomized when all eligibility criteria are met, and consent has been obtained.

10.4 Evaluation Procedures

Once participants meet all the inclusion, none of the exclusion criteria and are randomized, participants will go through the activities below.

Steps	Activity 1 (Prior to placing the device)
1.1	After enrollment and completion of baseline data collection, the participant will be escorted to a test room. Participant will be asked to remove all clothing and change into a gown. The participants may leave on a shirt if desired. • Female participants may keep on a bra if desired • Male participants – Unless the participant arrives to the clinical site with their pubic hair pre-trimmed, the participant's pubic hair will be clipped by themselves (or guardian/parent) or the HCP.
1.2	Prior to the participant's arrival to the test room, the bed will be prepared with clean sheets. A pre-weighed absorbent pad will be placed in the middle of the bed. A pre-weighed canister (weighed with lid) will be will be available for the participant to connect.
Note to site	Make sure top of mattress and PUCS height remains the same for all participants in the study.
1.3	The participant will be trained on device use per the Instructions for Use and a training video. The participant will be allowed to refer to any of the training materials that are available and provided to them throughout the study procedures.
1.4	The HCP will set-up the PUCS per the IFU. The HCP will confirm proper assembly by performing the following: • check that the PUCS lid is securely snapped. • check that all tubing and elbow connections on the lid are secure. • confirm power connections are secure. • ensure the Green LED light on the power switch is on. The HCP will adjust the PUCS as needed prior to continuing to next steps.
1.5	The participant will be asked to lie on their back on the bed and to leave their hands resting on their stomach, when possible, while they are lying on their back. For participant comfort, the head of the bed will be slightly elevated.
1.6	The participant (or guardian/parent) or HCP will clean the participant's anatomy with the provided wipes. The HCP will confirm the participant cleaned their anatomy.

1.7	The HCP will perform a skin integrity check and note any existing signs or symptoms of irritation in the perineal area. If the participant's skin is compromised, the HCP will consult the site staff before proceeding with placement of study device and/or withdraw the participant. HCP will confirm if no signs or symptoms of irritation in the perineal area was noted.
Steps	**Activity 2 (Placement of device)**
2.1	The participant will be given either the PureWick™ Male External Catheter (male participants only) or PureWick™ Flex Female External Catheter (female participants only).
2.2	***For female participants only:*** The participant (or guardian/parent) or HCP will curve the PW Flex to fit the participant's anatomy per the IFU.
2.3	The PW MEC or PW Flex will be connected to the canister via collector tubing per the IFU. Tubing connection to be done by the participant (or guardian/parent) for the self-placed void and by the HCP for the HCP-placed void. The HCP will confirm and record if the tubing connection was made correctly for the self-placed void. If the connection was not done correctly, the HCP will capture the reason: 1. The participant did not understand how to make the connection 2. The participant connected the device to the wrong tubing port 3. The participant was not physically able to make the connection with sufficient force 4. Other, specify The HCP will adjust tubing connection prior to void if it was not done correctly.
2.4	Based off the randomization of placement sequence, the participant will self-place (or guardian/parent) the device or the HCP will place the device.
2.5	If device was self-placed (or guardian/parent), the HCP will confirm the placement of the PureWick™ Male External Catheter (male participants only) or PureWick™ Flex Female External Catheter (female participants only). If the device is not placed correctly, the HCP will ask the participant to reposition/adjust the device. The HCP will record if any adjustments were made. Even when placed correctly, participants may adjust the device as needed for comfort. The HCP will record if any adjustments were made.
Steps	**Activity 3 (Void #1)**
3.1	The HCP will confirm that the absorbent bed pad is appropriately positioned under the participant.
3.2	The participant will be asked to void in the supine position. The participant will be instructed not to strain or attempt to regulate their urine flow.
Steps	**Activity 4 (Removing the device)**
4.1	After the completion of the void the participant (or guardian/parent) or HCP (based off placement sequence) will carefully remove the device per the instructions for use. • For female participants, HCP will record if the device has dislodged after the void prior to device removal
4.2	The HCP will record whether they observed any urine leak from the device upon removal.

4.3	The HCP will lift the catheter and tubing to make sure all the liquid flows into the canister.
4.4	The HCP will perform a skin integrity check and note any signs of irritation in the perineal area or adverse reactions. HCP will confirm if no signs or symptoms of irritation in the perineal area were noted.
4.5	The HCP will turn the PUCS suction OFF by flipping the black switch on the PUCS.
4.6	The used absorbent pad will be weighed by the HCP, and the value documented on the appropriate CRF. The canister (with lid) with urine will be weighed by the HCP and documented. The used catheter will be disconnected from the tubing and discarded.
4.7	The participant will be asked to complete all applicable questionnaires.
Steps	**Activity 5 (Void #2)**
5.1	After completion of void 1, the participant will be instructed to drink fluids in preparation for void 2.
5.2	Approximately 30 minutes after void 1 or when the participant feels the need to void again, the participant will proceed with void 2 (the participant will not use the same wetted device but a new clean device). Steps in Activities 1-4 will be repeated for the 2nd void based off the placement sequence.
Steps	**Activity 6 (After Completion of Both Voids)**
6.1	Once the participant has completed both voids, the participant will be asked to complete the remaining required questionnaire.
6.2	Each HCP will complete the ease-of-use questionnaire after completing all study activities.

Questionnaires to be completed

Person to complete questionnaire	Questionnaire to complete	When to complete
Participant	Perception of wetness	After each void
Participant	Ease of use	After self-placement void
Participant	Comfort	After completion of all voids
Participant	IFU Evaluation	After self-placement void
HCP	Ease of use	After completion of all participants. Each HCP completes this questionnaire once per device.

10.5 Safety Assessments

All AEs will be captured and summarized.

10.6 Follow-up Procedures

After all study assessments and procedures are complete, the participant will be discharged from the study. The 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.

11.0 STATISTICAL METHODS

There is no formal hypothesis testing, and no formal statistical test will be conducted. Participants responses will be complied and analyzed using descriptive statistics.

11.1 Sample Size Considerations

The study sample size requires a minimum of 20 males and 20 female healthy participants. This is considered adequate to assess the primary objective.

11.2 Analysis Population

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

Population	Description
Enrolled	All participants who sign the ICF
Intent-to-Treat (ITT)	All participants who have device placed for at least one void.
Per-Protocol (PP)	ITT subjects without any major protocol deviations

11.3 General Considerations

As there is no formal hypothesis testing, no formal statistical analysis will be conducted. Endpoints will be summarized using descriptive statistics.

11.4 Final Analysis

11.4.1 Primary Endpoint(s)

Capture Rate

Capture rate is defined as:

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

Voids with a total volume (captured urine + urine leak) of 10 mL is considered evaluable for this endpoint. Summary statistics such as mean, standard deviation, median, and range will be used for the analysis of capture rate. Separate summary may be provided by gender and by placement (HCP or self).

Perception of Wetness

Response to the questionnaire will be summarized as categorical variable and as continuous variable. Summary statistics such as frequency count, mean, standard deviation, median, and range will be provided. Separate summary may be provided by gender and by placement (HCP or self).

11.4.2 Secondary Endpoint(s)

Secondary endpoints will be summarized as categorical variable and as continuous variable. Summary statistics such as frequency count, mean, standard deviation, median, and range will be provided.

Ease of use score

Summary statistics will be provided for subjects and for HCPs separately.

Overall comfort score

Overall summary and summary by gender will be provided.

IFU comprehension score

Overall summary will be provided.

11.4.3 Tertiary/Exploratory Endpoint(s)

Not Applicable – There are no tertiary or exploratory endpoint

11.4.4 Other Analyses

Not Applicable – No other analyses will be performed outside of the statistical analysis plan

11.5 Interim Analysis

Not Applicable – The study does not have any interim analysis planned

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. Participants personal information will be 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 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 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

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.

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 (favorable opinion) from the respective IRB/EC 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,

- Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Parts 11, 50, 54, 56 and 812,
- 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,
- Applicable sections of the local laws and regulations.

18.0 INFORMED CONSENT PROCESS AND OTHER ETHICAL/REGULATORY CONSIDERATIONS

18.1 Informed Consent

18.1.1 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.

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

18.2 IRB/EC Approval

18.2.1 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.

18.2.2 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.

18.2.3 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 the IRB withdraws approval of the study prior to

completion, the Sponsor should be notified immediately, followed by a copy of the IRB/EC 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

18.3.1 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.

18.3.2 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.

18.3.3 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.

19.1.2 Serious Adverse Events (SAEs)

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 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.

19.1.8 Severity of Adverse Events

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

Severity Rating	Description
Mild	Event, signs, or symptoms that do not interfere with the participant'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 participant'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 participant and/or interferes with the participant's daily activity. Requires medical intervention and/or treatment to preclude a permanent impairment; may be life threatening and/or require hospitalization.

19.2 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.

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

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

19.2.2 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.

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.

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.

19.3 Reporting of Events

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.

19.3.1 Report by Investigator to Sponsor and IRB/EC

For all adverse events, all sections of the appropriate Case Report Form (CRF) must be completed.

- All SAEs, SADEs, UADEs/USADEs, and Serious Health Threats must be reported to the Sponsor no later than 1 calendar days of the clinical site/investigator becoming aware of the event.
- All AEs must be reported to the Sponsor no later than 1 calendar days.
- All device deficiencies must be report to the Sponsor no later than 1 calendar days.
- 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.

19.4 Safety Committees

19.4.1 Medical Monitor

19.5 The medical monitor is responsible for providing medical expertise and safety oversight for the study. The medical monitor is to ensure the welfare and safety of participants.

19.5.1 Clinical Events Committee

19.6 Not Applicable – This study will not utilize a clinical event committee as this is a non-significant risk IDE study.

19.6.1 Data Monitoring Committee

19.7 Not Applicable – This study will not utilize a data monitoring committee as there is no major morbidities studied.

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/EC, and all Investigators and 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.

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 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.

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

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 following documentation should be received by the Sponsor prior to the commencement of study activities:

- Fully executed Confidentiality Disclosure Agreement,
- Fully executed Work Order/Mast Clinical Trial Agreement,
- 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 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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25.0 VERSION HISTORY

Ver. #	Date (DD-MMM-YYYY)	Change Owner	Description and Justification of Change
1.0	09-AUG-2024	Ajesh Raju	Original

26.0 APPENDICES

26.1 Appendix 1 - PureWick™ Male External Catheter

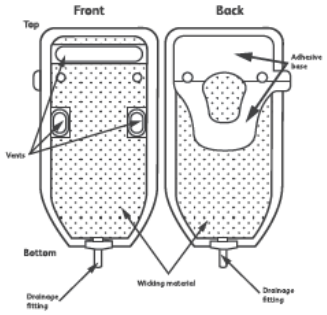
en

BD PureWick™ Male External Catheter

Instructions for Use

Items needed for application (not included):
Trimmers or Clippers
Soap and water wipes
Drying towel

START HERE: Wash your hands before and after this procedure. If placing or removing this product on another person, wear gloves. Please read instructions, warnings, precautions, and recommendations entirely before placing the device.



Indications for use:
The device is intended for non-invasive urine output management, such as urinary incontinence, in users with male anatomy.

Contraindications:
- Users with urinary retention.

Warnings:
- Do not use on irritated skin. Examples include, but are not limited to, rashes, skin tears, or blisters.
- Do not cover fresh surgical wounds with the device.
- Do not use the device with any material or in any position that blocks the vents on the front of the device or does not allow for airflow through the device. Examples include, but are not limited to, tight clothing or briefs.
- To avoid potential skin injury, never pull the device directly away from the user. Always peel in the direction from head to foot.
- Stop use if an allergic reaction occurs.
- After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.

Precautions:
- Not recommended for users who:
  - Are agitated, combative, or uncooperative and might remove the device.
  - Have frequent episodes of bowel incontinence without a fecal management system in place.
  - Have skin irritation or breakdown at the site.
- Do not use barrier creams, lotions, or ointments on the penis or pubic skin around the base of the penis when using the device. These may impede suction or weaken adhesive.
- Proceed with caution in users who have had recent surgery of the external male anatomy.
- Always check skin for irritation or breakdown and clean and dry the skin prior to placement of a new device.

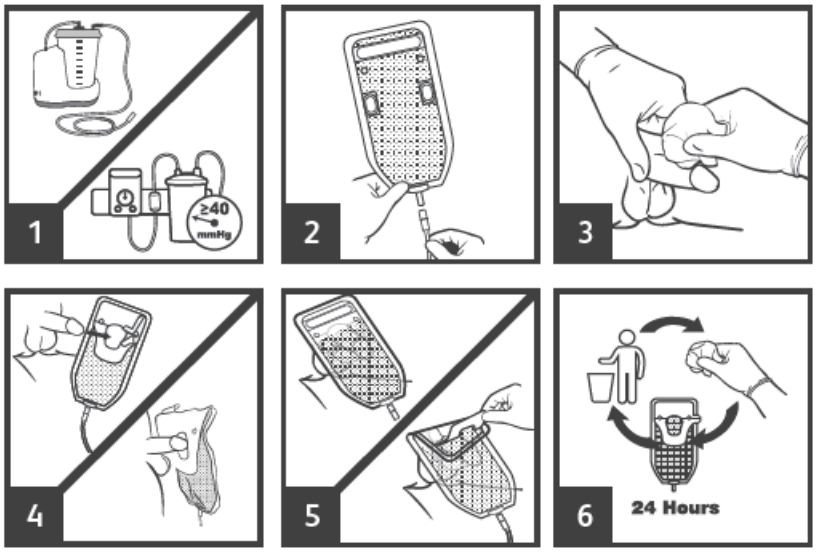
Recommendations:
- Wash hands thoroughly before device placement.
- Ensure the device remains connected after turning the user, monitoring for pulling and tension on the device.
- Remove the device prior to walking.
- Check device placement and user's skin at least every 2 hours.
- Refer to the PureWick™ Urine Collection System IFU for instructions on suction tubing replacement.

SYMBOL	SYMBOL TITLE (STANDARD REFERENCE)	EXPLANATORY TEXT
Symbols immediately below are derived from the following standard: ISO 15223-1:2021 - Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.		
	Manufacturer (5.1.1)	Indicates the medical device manufacturer
LOT	Lot number (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	Catalog number (5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified
	Use by (5.1.4)	Indicates the date after which the medical device is not to be used
	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process
	Do not use if package is damaged and consult instructions for use (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Single use (5.4.2.)	Indicates a medical device that is intended for one single use only
	Consult instructions for use or consult electronic instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use
Symbols immediately below are derived from the following standard: ISO 7000 – Graphical symbols for use on equipment		
	Packaging unit (2794)	To indicate the number of pieces in the package
Other		
NRL	Not made with Natural Rubber Latex	Indicates that the medical device is not made with natural rubber latex

Template GFM-10095B

en

BD PureWick™
Male External Catheter



PureWick™ Urine Collection System Setup

1. Please consult the PureWick™ Urine Collection System Instructions for Use as needed. Confirm the PureWick™ Urine Collection System, collection canister, and tubing are set up correctly. Turn the unit ON, using the ON/OFF switch.
   NOTE: *Ensure all connections are air-tight and check for possible cracks, leaks, kinks, or blockages.*
2. Securely connect the drainage fitting of the PureWick™ Male External Catheter to the open end of the collector tubing on the PureWick™ Urine Collection System.

Placement of PureWick™ Male External Catheter

3. Trim or clip the pubic hair to ensure the product securely adheres to the skin. Check the skin and do not use if there is irritation or breakdown. Clean the penis and the skin around the base of the penis with soap and water or soap and water wipes. Dry skin prior to positioning the device.
   NOTE: *Moisture or soap residue on skin will weaken the adhesive.*
4. Position the device, aligning drainage fitting towards the feet of the user. Slide the opening of the device over the penis until close to, but not touching, the skin around the base of the penis. Center penis within the opening. Do not place scrotum inside the device. Remove the bottom adhesive peel-off and press the device against the skin below the base of the penis. Remove the top adhesive peel-off and press the device against the skin above the base of the penis. Ensure device has fully adhered around the base of the penis by pressing down on the adhesive.

Removal of PureWick™ Male External Catheter

5. Gently lift the top edge of the adhesive base off the skin. In a slow, downward peeling motion, remove the device. If necessary, use a warm, wet cloth or pad to help loosen adhesive.
   Warning: *To avoid potential skin injury, never pull the device directly away from the user. Always peel in the direction from head to foot.*

   After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.

When to Replace PureWick™ Male External Catheter

6. Replace the device at least every 24 hours or if soiled with feces, blood, or semen.

Wall Suction

This product is compatible with wall suction in hospital-like settings. If using this set-up, connect the canister to wall suction and set to a minimum of 40 mmHg continuous suction. Always use the minimum amount of suction necessary.

Manufacturer:
C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014 USA
1.844.823.5433
bd.com

BK76[illegible] 10/2023

26.2 Appendix 2 - PureWick™ Flex Female External Catheter

SYMBOL	SYMBOL TITLE (STANDARD REFERENCE)	EXPLANATORY TEXT
Symbols immediately below are derived from the following standard: ISO 15223-1:2021 - Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.		
	Manufacturer (5.1.1)	Indicates the medical device manufacturer
LOT	Lot number (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	Catalog number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Use by (5.1.4)	Indicates the date after which the medical device is not to be used
NON STERILE	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process
	Do not use if package is damaged and consult instructions for use (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Single use (5.4.2)	Indicates a medical device that is intended for one single use only
ifu.bd.com	Consult instructions for use or consult electronic instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use
Symbols immediately below are derived from the following standard: ISO 7000 – Graphical symbols for use on equipment		
	Packaging unit (2794)	To indicate the number of pieces in the package
Symbols immediately below are derived from the following standard: ASTM F2503 – Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment		
MR	Magnetic Resonance (MR) Conditional (7.4.6.1)	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.
Other		
NRL	Not made with Natural Rubber Latex	Indicates that the medical device is not made with natural rubber latex

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bd.com
purewickathome.com

PK2459599 12/2023

BD PureWick™ Flex
Female External Catheter
Instructions for Use

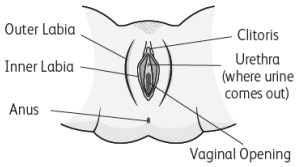
Indications
The PureWick™ Flex Female External Catheter is intended for non-invasive urine output management in adult users with female anatomy, for conditions such as urinary incontinence.

Contraindications
Users with urinary retention.

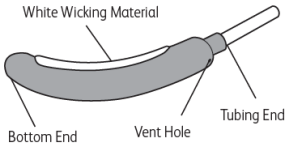
Warnings
- The PureWick™ Flex Female External Catheter is designed for single-use only. Trying to wash, sanitize or reuse it may lead to risk of infection or illness. This may damage the product and materials. The product may not work and cause injury or illness.
- To avoid potential skin injury, never push or rub the product against the skin during placement or removal.
- Do not block airflow to the product (e.g., blocking the vent hole, bedpan, barrier creams)
- Do not insert the product into vagina, anus, or other body orifice.
- Stop use if an allergic reaction occurs.
- After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.
- Do not use on users with frequent episodes of stool incontinence without a fecal management system in place.
- Do not use on users with skin irritation or breakdown at the site.
- Use with caution on users who had recent surgery of the external female anatomy.
- Do not use on users with moderate/heavy menstruation who cannot use a tampon.

MRI Warnings
- **Always disconnect the PureWick™ Flex Female External Catheter from wall suction or the PureWick™ Urine Collection System prior to an MRI procedure.**
- **It is important to closely follow these specific conditions that have been determined to permit the examination to be conducted safely. Any deviation may result in injury to the user.**
- Non-clinical testing demonstrated that the PureWick™ Flex Female External Catheter is MR Conditional. A user with one of these PureWick™ Flex Female External Catheters can be scanned safely under the following conditions:

THE FEMALE ANATOMY



THE PRODUCT



- Static magnetic field of 1.5-Tesla or 3-Tesla only
- Maximum spatial gradient magnetic field of 40-T/m (4000-Gauss/cm)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2-W/kg for up to 60 minutes of continuous scanning in the Normal Operating Mode
- Under the scan conditions defined, the PureWick™ Flex Female External Catheter is expected to produce a maximum temperature rise of 1.5 degrees Celsius after 15-minutes of continuous scanning.
- There are no circularly polarized (quadrature-driven) RF coil restrictions.

Precautions

- Use with caution on users who are agitated, combative or uncooperative and might remove the product.
- Do not use barrier cream on the surfaces where the product will be placed. Barrier cream may reduce suction.
- Keep suction on while removing the product. This helps prevent leaks during removal.

Recommendations

- Check position of the product after repositioning the user.
- Users may transition (e.g., bed to chair), but the product should be removed if they are up and walking.
- Reposition the product and check the user's skin at least every 2 hours.
- Placing the product snugly between the inner labia and buttocks holds it in place for most users. Breathable underwear may be useful for securing the product for some patients.
- Change the suction tubing and canister per facility protocol or per PureWick™ Urine Collection System Instructions for Use.
- Before connecting the product to facility wall suction tubing, verify suction function by covering the open end of the suction tubing with one hand and looking at the pressure dial. If the pressure does not increase when the line is covered, make sure that the tubing is secured, connected, and not kinked.

Instructions for Use

Wash hands before and after this procedure. If placing or removing this product for another person, wear gloves.

Setup

1 **If using continuous wall suction**, always use the minimum amount of suction necessary. Connect the canister setup per facility protocol. Set suction to 40 mmHg and adjust as needed. Different setups require higher suction typically between 60-100 mmHg.

NOTE: *If hospital policy allows and if using a graduated canister, captured urine may be used for approximate urine output measurement.*

If using the PureWick™ Urine Collection System, make sure all tubing connections are snug, and **turn it on**. Pressure adjustments are not necessary. Consult the PureWick™ Urine Collection System Instructions for Use as needed.

NOTE: *Ensure all connections are air-tight and check for possible cracks, leaks, kinks, or occlusions.*

2 Before placing the product, curve it to fit the user's anatomy. This helps the product stay in place.

3 **If using continuous wall suction**, securely connect the product to the suction tubing.

NOTE: *Keep track of how long the product has been in place by writing down the date and time it was placed.*

If using the PureWick™ Urine Collection System, securely connect the PureWick™ Flex Female External Catheter to the collector tubing.

Placement

4 Have the user lie on their back with knees bent and thighs apart (frog legged) or on their side before placing the product.

With their legs open, check the skin for irritation or breakdown, and clean the female anatomy.

NOTE: *If skin irritation or breakdown is seen, do not use the product.*

5 Spread the inner labia and keep them spread while placing the product.

With white wicking material side facing the user, place the bottom end of the product between the buttocks, but not as far back as to cover the anus.

Gently tuck white wicking material side between the inner labia, directly against the urethra (where the urine comes out).

NOTE: *Make sure the urethra is at least one inch down from the top of the white wicking material.*

6 Make sure the inner labia wrap **around** the product and are not tucked under it.

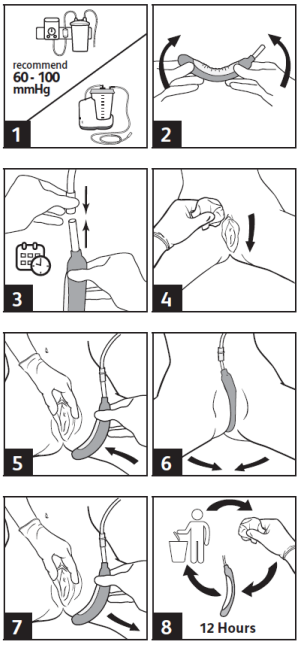
Once the product is in place, slowly close the legs and **make sure the vent hole is not covered**. See product diagram on page 1 for vent hole location.

NOTE: *For users with **larger** labia, less of the product will be visible. For users with **smaller** labia, more of the product will be visible.*

Removal

7 Open the legs and gently spread the labia. Gently pull the product away from the body. Keep suction on while removing the product.

After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state, and federal laws and regulations.



Maintenance:

8 Replace the product every 12 hours or if soiled with feces or blood.

26.3 Appendix 3 - PureWick™ Urine Collection System

BD PureWick™

Urine Collection System

USER GUIDE AND
LIMITED PRODUCT WARRANTY

For use with
PureWick™ External Catheters

PW100 (corded only)
PW200 (with lithium-ion battery)

Welcome

Thank you for purchasing the PureWick™ Urine Collection System, the system to be used with PureWick™ External Catheters. The device pulls urine through tubing that is connected to a collection canister. Urine is stored in the collection canister for proper disposal. This product may be used in both home environments and professional care facilities.

Please read all operating instructions and warnings before the first use of this product. No special skills or additional training is required.

Intended Users

The PureWick™ Urine Collection System is intended to be operated by:

- User/Patient
- Caregiver/Healthcare professional

All functions can be safely performed by the individuals above.

Indications for Use

The PureWick™ Urine Collection System is to be used with PureWick™ External Catheters which are intended for non-invasive urine output management.

Contraindications for Use

Do not use the PureWick™ Urine Collection System with PureWick™ External Catheters on individuals with urinary retention.

Safety and Warnings

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.

WARNING: Contains small parts that may cause choking. Keep out of reach of children.

Keep cords and tubing out of the reach of children to avoid the risk of strangulation.

Discontinue use if an allergic reaction occurs. Not recommended for users who are experiencing skin irritation or skin breakdown in device contact areas.

WARNING: This device should not be used in oxygen rich environments or in conjunction with flammable anesthetics.

If the PureWick™ Urine Collection System is dropped or tipped over spilling urine, unplug the unit and carefully inspect for loose or damaged parts before resuming use. Contact Customer Support at 1-888-201-1586 if any damage is observed.

The pump tubing connecting the PureWick™ Urine Collection System to the collection canister may experience light condensation inside the tube. This is not unusual and does not affect function. However, if urine or water has streamed into the pump, discontinue use and contact Customer Support at 1-888-201-1586.

Although the canister can hold up to 2000cc (mL), the urine should be emptied regularly from the collection canister before volume reaches 1800cc (mL). Failure to empty canister before urine overflow may cause damage to the PureWick™ Urine Collection System and is not covered under the warranty.

It is important that the port connections be connected correctly for proper operation of the PureWick™ Urine Collection System.

Use of this equipment next to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30cm) to any part of the PureWick™ Urine Collection System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use only PureWick™ Urine Collection System accessories with this device. Incompatible parts or accessories can result in degraded performance and will void the warranty.

Do not use accessories past expiration date indicated on package labeling.

Use only the PureWick™ Urine Collection System A/C power cord with the device. Use of an alternate consumer style A/C power adapter or an extension cord may cause damage to device and electrical shock or injury and will void the warranty.

Do not place PureWick™ Urine Collection System or its cord across walkways creating a tripping hazard.

For PW200: The battery cells used in this device may present a fire or chemical hazard. To minimize the risk of damaging the battery inside the PureWick™ Urine Collection System, do not use the device outside the indicated operating temperature range of 41°F - 104°F (5°C - 40°C). The battery is not intended to be replaced; replacement could result in a hazard.

TO REDUCE THE RISK OF ELECTRICAL SHOCK OR INJURY, DO NOT DISASSEMBLE THIS UNIT. NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

KIT CONTENTS

Reusable Items:	Single Patient Multiple Use Items (Accessories):
• PureWick™ Urine Collection System, with or without battery (1)	• 2000cc (mL) Collection Canister with Lid (1)
	• Collector Tubing with Elbow Connector (1)
• A/C Power Cord (1)	• Pump Tubing (1)
• User Guide (1)	• Privacy Covers (2)

Initial Setup

1. Inspect the package for damage. If any damage is noticed, contact Customer Support at 1-888-201-1586 immediately.
2. Carefully remove all contents from the package, including the packing material and inspect prior to use. If any damage is noticed, contact Customer Support at 1-888-201-1586 immediately.
3. Place the PureWick™ Urine Collection System (A) next to the bed or chair where it will be used. It must be close enough for the collector tubing with elbow connector (G) to easily reach the user and should be placed on a stable, even surface. For optimal results, position the PureWick™ Urine Collection System either on the floor or as close to the floor as your facility's protocol will allow.

   Note: The PureWick™ Urine Collection System should be stationary while in use. Device is not designed to be used while in transport.

   CAUTION: Avoid creating a tripping hazard with the collector tubing or power cord.
4. Plug the PureWick™ Urine Collection System power cord into device outlet (B) and into an A/C power outlet.

   Note: The device should be positioned for easy access to the A/C inlet and power cord.

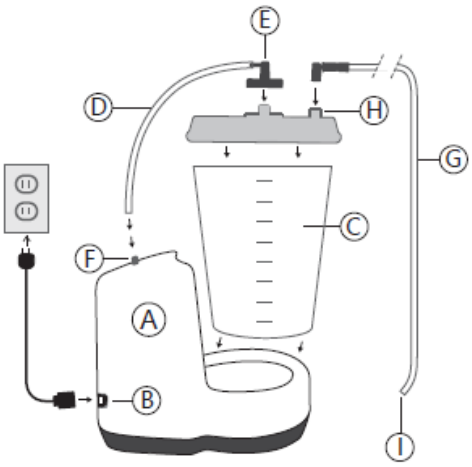
   Note: Make sure the power switch is turned off before connecting the power cord.

   - **Battery Power Operation (PW200 Only)**
     The built-in battery recharges any time the device is plugged into an outlet. To fully charge the battery, the system must be plugged in for 12 hours. The battery will supply 8 hours of backup power before requiring recharging. The PureWick™ Urine Collection System remains fully functional while the device is recharging.

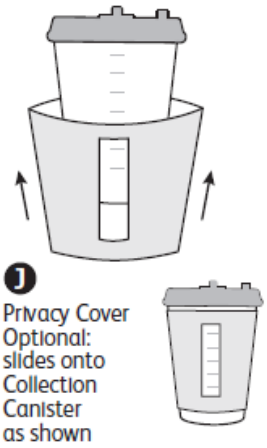
Battery Life Status - Green LED Light	
No Light	Device is powered off
Solid	Device is on and fully charged
Slow Blink	Device is charging
Fast Blink	Operating on battery; battery less than 20%

Note: If it is too cold or hot, charging time may be longer or battery may not fully charge.

5. Place the collection canister (C) in the PureWick™ Urine Collection System base and press down firmly on the lid making sure the lid is sealed. Optional (prior to sealing canister lid): While operating the PureWick™ Urine Collection System, ammonia odor for up to 1800 mL of urine can be eliminated by adding 2 teaspoons (10 grams) of vitamin C (ascorbic acid) powder into the collection canister before use. At least 99.93% of pure vitamin C (ascorbic acid) is recommended. If using the privacy cover (J), slip privacy cover onto canister (similar to a coffee cup sleeve) prior to placing canister into the base. Attach the pump tubing (D) to the PureWick™ Urine Collection System connector port (F) and the connector port (E) on the collection canister lid.



A PureWick™ Urine Collection System
B Device electrical cord port
C 2000cc (mL) Collection canister with lid
D Pump tubing
E Pump tubing port to canister
F Connector port for pump tubing
G Collector tubing with elbow connector
H Connector port for collector tubing
I Attach PureWick™ External Catheter (sold separately)



J Privacy Cover Optional: slides onto Collection Canister as shown

6. Attach the collector tubing (G) to the connector port (H) on the collection canister lid.

   CAUTION: It is important that the port connections be connected correctly and securely for proper operation of the PureWick™ Urine Collection System.

7. Turn on the PureWick™ Urine Collection System by pressing the ON/OFF switch. The PureWick™ Urine Collection System is working when the switch lights up green and the device makes a soft humming sound.

8. Connect the other end of the collector tubing securely to a PureWick™ External Catheter (I). The system is now ready for use.

Operating Instructions

1. After the PureWick™ Urine Collection System has been set up, place the PureWick™ External Catheter according to the PureWick™ External Catheter's instructions for use.

2. When the canister is ready to be emptied, remove the PureWick™ External Catheter according to the PureWick™ External Catheter's instructions for use and throw away.

   Note: Keep the PureWick™ Urine Collection System ON to make sure all urine has been drawn out of the collector tubing and into the collection canister before removing the PureWick™ External Catheter.

   Note: Although the canister can hold up to 2000cc (mL), to prevent overflow empty urine from the collection canister regularly or before volume reaches 1800cc (mL).

3. Turn off the PureWick™ Urine Collection System by pressing the ON/OFF switch. Disconnect the A/C power cord from the power outlet and from the device. Disconnect collector tubing and pump tubing from the canister.

4. Lift collection canister from PureWick™ Urine Collection System. **Do not lift canister by the lid.** Take canister into an area appropriate for disposal e.g. a bathroom, carefully remove the lid, and dispose of urine in a proper receptacle e.g. a toilet or according to facility protocol. If using a privacy cover and it gets wet, remove and discard.

5. Clean collector tubing, pump tubing, canister, canister lid, PureWick™ Urine Collection System, and power cord according to cleaning instructions in the Cleaning and Maintenance section.

6. Reassemble the PureWick™ Urine Collection System according to the Initial Setup instructions when the system is ready to be reused.

When the PureWick™ Urine Collection System is not in use, unplug the power cord from its outlet. Make sure the unit is cleaned and disinfected prior to storage. Do not store when parts are wet or damp.

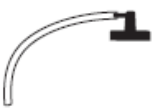
Cleaning and Maintenance

Inspect the PureWick™ Urine Collection System and accessories for damage or wear prior to use and replace as necessary.

DO NOT ATTEMPT TO OPEN OR DISMANTLE THE PUREWICK™ URINE COLLECTION SYSTEM. THIS MAY AFFECT PERFORMANCE, CREATE A POTENTIAL SAFETY HAZARD, CAUSE PERSONAL INJURY, AND WILL VOID THE WARRANTY.

ALWAYS TURN OFF THE DEVICE AND DISCONNECT FROM POWER SOURCE PRIOR TO CLEANING.

THE PRIVACY COVER COMPONENTS ARE SINGLE USE ONLY AND SHOULD NOT BE CLEANED OR DISINFECTED.

	Collection Canister and Lid	Collector Tubing with elbow connector	PureWick™ Urine Collection System base	Pump Tubing	Power Cord
					
Frequency: Daily	✓ Clean ✓ Disinfect	✓ Clean ✓ Disinfect	✓ Clean ✓ Disinfect	✓ Clean ✓ Disinfect	✓ Clean ✓ Disinfect
USE CASE	Single Patient Multiple Use	Single Patient Multiple Use	Reusable	Single Patient Multiple Use	Reusable

Point of Use Cleaning: After the completion of each use, the collection canister, canister lid, collector tubing, and pump tubing should be rinsed with cool tap water to remove any residual debris or dirt. The PureWick™ Urine Collection System base should be wiped with a clean low lint cloth dampened with cool tap water.

Manual Cleaning Instructions for Single User (Home Care):

The collection canister, canister lid, collector tubing, pump tubing, and PureWick™ Urine Collection System base should be cleaned and disinfected at the time of each use, or at a minimum, daily. The power cord should be cleaned and disinfected at the time of each use, or at a minimum daily.

Note: Gloves should be worn when handling soiled or dirty accessories.

Canister and Canister Lid

- **Initial Rinse:** Rinse the canister and lid thoroughly with cool tap water. While rinsing, remove any excess dirt by wiping the canister and lid with disposable low lint wipes.

- **Cleaning:** Prepare a soapy solution by mixing 1 teaspoon (approximately 5 mL) of dish soap with 1 gallon (approximately 4 L) of cool tap water. Fully submerge canister and lid in the solution. Allow it to sit for a minimum of ten (10) minutes. While submerged, use a soft brush (e.g. toothbrush) to brush all accessible areas of the canister and lid for a minimum of one (1) minute to remove any visible signs of debris or dirt.
- **Rinse:** Rinse the canister and the lid thoroughly with cool tap water until there is no visible sign of the cleaning solution.
- **Visual inspection:** Inspect the canister and the lid to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat steps above until there is no sign of debris or dirt remaining on the canister and lid.
- **Disinfection:** Fully submerge the canister and lid in 70% isopropyl alcohol (IPA). Allow it to sit for a minimum of ten (10) minutes.

  OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Fully submerge the canister and lid in the solution. Allow it to sit for a minimum of forty-five (45) minutes.
- **Rinse:** Rinse the canister and the lid thoroughly with cool tap water.
- **Drying:** Dry the canister and lid with a clean low lint towel or cloth.

Collector Tubing (with elbow connector) and Pump Tubing

- **Initial Rinse:** Disconnect the collector tubing from the elbow connector and disconnect the elbow connector from the lid. Rinse the disconnected tubing thoroughly by running cool tap water through the inside of the tubing. While rinsing, remove any excess dirt by wiping the outside of the tubing and elbow connector with low lint disposable wipes. While rinsing, flush the tubing with cool tap water to remove any excess dirt.
- **Cleaning:** Prepare a soapy solution by mixing 1 teaspoon (approximately 5 mL) of dish soap with 1 gallon (approximately 4 L) of cool tap water. Completely submerge the tubing and elbow connector in the solution and allow it to soak for a minimum of ten (10) minutes. At the beginning of the soak time, flush the inside of the tubing with the prepared solution. While submerged, use a soft brush (e.g. toothbrush) to brush all accessible areas of the tubing and elbow connector for a minimum of one (1) minute to remove any visible signs of debris or dirt.
- **Rinse:** Rinse the tubing and elbow connector thoroughly with cool tap water until there is no visible sign of the soap cleaning solution. While rinsing, flush the inside of the tubing with the tap water.
- **Visual inspection:** Inspect the tubing to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat the steps above until there is no sign of debris or dirt remaining on or inside the tubing.
- **Disinfection:** Fully submerge the tubing and elbow connector in 70% isopropyl alcohol (IPA). Allow it to soak for a minimum of ten (10) minutes. Flush the IPA through the tubing, prior to starting the ten (10) minute time.

OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Fully submerge the tubing and elbow connector in the diluted disinfection solution. Allow it to soak for a minimum of forty-five (45) minutes. Flush the diluted disinfection solution through the tubing, prior to starting the forty-five (45) minute time.

- **Rinse:** Rinse the tubing and elbow connector thoroughly with cool tap water, ensuring that the inside of the tubing is flushed with water.
- **Drying:** Dry the tubing and elbow connector outer surface with a clean low lint towel or cloth and allow the inside of the tubing to air dry for a minimum of thirty (30) minutes at room temperature.

PureWick™ Urine Collection System Base with power cord

- **Initial Wipe:** Wipe the PureWick™ Urine Collection System base and power cord thoroughly with a clean low lint cloth dampened with cool tap water. Remove any excess dirt by wiping the device with disposable low lint wipes.
- **Cleaning:** Prepare a soapy solution by mixing 1 teaspoon (approximately 5 mL) of dish soap with 1 gallon (approximately 4 L) of cool tap water. Completely wet a clean low lint cloth with the solution and wipe down the PureWick™ Urine Collection System base and power cord. Allow the cleaning solution to remain on the device and power cord for a minimum of ten (10) minutes, ensuring that the device and power cord remains wet for the ten (10) minutes. Using a soft brush (e.g. toothbrush), brush all accessible areas of the PureWick™ Urine Collection System base and power cord for a minimum of one (1) minute to remove any visible signs of debris or dirt.
- **Rinse:** Using a new clean low lint cloth, wipe the PureWick™ Urine Collection System base and power cord thoroughly with cool tap water to remove the soap cleaning solution. Perform this step until there is no visible sign of the soap cleaning solution.
- **Visual inspection:** Inspect the PureWick™ Urine Collection System base and power cord to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat the steps above until there is no sign of debris or dirt remaining on the PureWick™ Urine Collection System base and power cord.
- **Disinfection:** Use 70% isopropyl alcohol (IPA) to completely wet a clean low lint cloth and wipe down the PureWick™ Urine Collection System base and power cord. Allow the disinfecting solution to remain on the device and power cord for a minimum of ten (10) minutes, ensuring the unit is visibly wet with IPA for ten (10) minutes.

  OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Use the diluted disinfecting solution to completely wet a clean low lint cloth and wipe down the PureWick™ Urine Collection System base and power cord. Allow the disinfecting solution to remain on the device and power cord for a minimum of forty-five (45) minutes, ensuring the unit is visibly wet with the diluted disinfecting solution for forty-five (45) minutes.

- **Rinse:** Using a new clean low lint cloth, wipe the PureWick™ Urine Collection System base and power cord thoroughly with cool tap water to remove the disinfecting solution.
- **Drying:** Dry the PureWick™ Urine Collection System base and power cord with a clean low lint towel or cloth.

Manual Cleaning Instructions for Hospitals and Long-Term Care Facilities:

Contamination should be assumed prior to use with a new user; therefore, the PureWick™ Urine Collection System base and power cord must be fully cleaned with a disinfectant before reuse. The collection canister and tubing are not suitable for reuse in a multiple user environment. A new collection canister and new tubing must be used for each new user.

Canister and Canister Lid (Single User)

- **Initial Rinse:** Rinse the canister and lid thoroughly with cool tap water. While rinsing, remove any excess dirt by wiping the canister and lid with disposable low lint wipes.
- **Cleaning:** Prepare enzymatic cleaner solution (e.g. Enzol Enzymatic Cleaner or equivalent) following the manufacturer's recommendation (ratio and water temperature per manufacturer's recommendation if applicable). Completely submerge the canister and lid in the solution and allow it to soak for a minimum of ten (10) minutes. While the canister and lid are submerged, use a soft bristle brush (e.g. toothbrush) to brush all accessible areas of the canister and lid for a minimum of one (1) minute to remove any visible signs of debris or dirt.
- **Rinse:** Rinse the canister and the lid thoroughly with cool tap water until there is no visible sign of the enzymatic cleaning solution.
- **Visual inspection:** Inspect the canister and the lid to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat the steps above until there is no sign of debris or dirt remaining on the canister and lid.
- **Drying:** Dry the canister and lid with a clean low lint towel or cloth.
- **Disinfection:** Fully submerge the canister and lid in 70% isopropyl alcohol (IPA). Allow it to sit for a minimum of ten (10) minutes.

  OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Fully submerge the canister and lid in the solution. Allow it to sit for a minimum of forty-five (45) minutes.
- **Rinse:** Rinse the canister and the lid thoroughly with cool tap water.
- **Drying:** Dry the canister and lid with a clean low lint towel or cloth.

Collector Tubing (with elbow connector) and Pump Tubing (Single User)

- **Initial Rinse:** Disconnect the collector tubing from the elbow connector and disconnect the elbow connector from the lid. Rinse the disconnected tubing thoroughly by running cool tap water through the inside of the tubing. While rinsing, remove any excess dirt by wiping the outside of the tubing and elbow

connector with low lint disposable wipes. While rinsing, flush the tubing with cool tap water to remove any excess dirt.

- **Cleaning:** Prepare enzymatic cleaner solution (e.g. Enzol Enzymatic Cleaner or equivalent) following the manufacturer's recommendation (ratio and water temperature per manufacturer's recommendation if applicable). Completely submerge the tubing and elbow connector in the solution and allow it to soak for a minimum of ten (10) minutes. At the beginning of the soak time, flush the inside of the tubing with the prepared solution. While the tubing is submerged, use a soft bristle brush (e.g. toothbrush) to brush all accessible areas of the tubing and elbow connector for a minimum of one (1) minute to remove any visible signs of debris or dirt.
- **Rinse:** Rinse the tubing and elbow connector thoroughly with cool tap water until there is no visible sign of the enzymatic cleaning solution. While rinsing, flush the inside of the tubing with the cool tap water.
- **Visual inspection:** Inspect the tubing to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat the steps above until there is no sign of debris or dirt remaining on or inside the tubing.
- **Disinfection:** Fully submerge the tubing and elbow connector in 70% isopropyl alcohol (IPA). Allow it to sit for a minimum of ten (10) minutes. Flush the IPA through the tubing, prior to starting the ten (10) minute time.

  OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Fully submerge the tubing and elbow connector in the diluted disinfection solution. Allow it to soak for a minimum of forty-five (45) minutes. Flush the diluted disinfection solution through the tubing, prior to starting the forty-five (45) minute time.
- **Rinse:** Rinse the tubing and elbow connector thoroughly with cool tap water, ensuring that the inside of the tubing is flushed with water.
- **Drying:** Dry the tubing and elbow connector outer surface with a clean low lint towel or cloth and allow the inside of the tubing to air dry for a minimum of thirty (30) minutes at room temperature.

PureWick™ Urine Collection System Base with power cord (Multiple Users)

- **Initial Wipe:** Wipe the PureWick™ Urine Collection System base and power cord thoroughly with a clean low lint cloth dampened with cool tap water. Remove any excess dirt by wiping the unit with disposable low lint wipes.
- **Cleaning:** Prepare enzymatic cleaner solution (e.g. Enzol Enzymatic Cleaner or equivalent) following the manufacturer's recommendation (ratio and water temperature per manufacturer's recommendation if applicable). Wipe the device and power cord with a low lint cloth dampened with the solution. Allow the device and power cord to remain wet for a minimum of ten (10) minutes, ensuring that the device and power cord are visibly wet for the ten (10) minutes. Using a soft bristle brush (e.g. toothbrush), brush all accessible areas of the PureWick™ Urine Collection System base and power cord for a minimum of one (1) minute to remove any visible signs of debris or dirt.

- **Rinse:** Using a new clean low lint cloth, wipe the PureWick™ Urine Collection System base and power cord thoroughly with cool tap water to remove the enzymatic cleaning solution. Perform this step until there is no visible sign of the cleaning solution.
- **Visual inspection:** Inspect the PureWick™ Urine Collection System base and power cord to ensure that all debris and dirt have been removed. If there is any sign of debris or dirt, repeat the steps above until there is no sign of debris or dirt remaining on the PureWick™ Urine Collection System base and power cord.
- **Disinfection:** Use 70% isopropyl alcohol (IPA) to completely wet a clean low lint cloth and wipe down the device and power cord. Allow the disinfecting solution to remain on the PureWick™ Urine Collection System base and power cord for a minimum of ten (10) minutes, ensuring the unit is visibly wet with IPA for ten (10) minutes.

  OR Prepare a disinfecting solution to yield a 0.1% sodium hypochlorite (bleach) solution, using manufacturer's recommendations if applicable. An example dilution for bleach that has a 5.25% initial concentration is to dilute 1/3 cup bleach with 1 gallon of cool water to yield a 0.1% sodium hypochlorite (bleach) solution. Use the diluted disinfecting solution to completely wet a clean low lint cloth and wipe down the PureWick™ Urine Collection System base and power cord. Allow the disinfecting solution to remain on the device and power cord for a minimum of forty-five (45) minutes, ensuring the unit is visibly wet with the diluted disinfecting solution for forty-five (45) minutes.
- **Rinse:** Using a new clean low lint cloth, wipe the PureWick™ Urine Collection System base and power cord thoroughly with cool tap water to remove the disinfecting solution.
- **Drying:** Dry the PureWick™ Urine Collection System base and power cord with a clean low lint towel or cloth.

Replacing Canister and Tubing

Replace the canister and tubing for each patient according to useful life:
- every 60 days for PWKIT03 canister and accessories (this kit includes a canister without handle)
- every 90 days for PWKIT03H canister and accessories (this kit includes a canister with handle)

If you notice any of the following, replace immediately:
- Canister or tubing has residual urine build-up
- Canister or tubing appear cloudy
- Canister or tubing appear discolored
- Canister becomes cracked
- Tubing becomes torn
- PureWick™ External Catheter no longer securely connects to collector tubing

Failure to clean and/or replace accessories may affect the performance of the system.

Troubleshooting

Symptom	Check the following
• The device does not turn on when external power is used • The power switch does not glow when turned on	1. Check that the power cord is plugged into the PureWick™ Urine Collection System and to an electrical outlet. 2. Ensure the electrical outlet is functioning by plugging in another electrical device.
• The device is on but is not suctioning properly	1. Ensure tubing connections are connected properly. 2. Check collector tubing for blockage or flow restriction such as pinched or kinked tubing. 3. Ensure overflow stop valve in collection canister lid is open. The valve floats to the top when the collection canister is full. The stop valve may close if the lid or canister is tipped sideways or upside down. Disconnect tubing and gently shake the lid to reset the valve down to the open position. 4. Ensure collection canister is sealed with the lid tightly closed. 5. Verify suction by disconnecting PureWick™ External Catheter from the collector tubing and placing the end of the collector tubing into a cup of water. If water easily flows into the collection canister replace the PureWick™ External Catheter.

There are no serviceable parts in the PureWick™ Urine Collection System. Adjustments or modifications made by anyone other than an authorized representative of BD will void the Warranty.

If the PureWick™ Urine Collection System is not functioning properly after performing the troubleshooting steps, the device may have reached the end of its useful life. With normal use, this device shall remain safe for the useful life. Do not use the device if it is damaged or defective, including, but not limited to the following:

- Cracks
- Separated housing
- Not suctioning properly or no suction
- Damaged power cord

If damage is noticed and the device is still under warranty, contact Customer Support at 1-888-201-1586 immediately.

Disposal

The PureWick™ Urine Collection System and accessories may be a potential biohazard. Clean and disinfect the PureWick™ Urine Collection System and accessories before disposal. Handle in accordance with accepted medical practice and applicable local and federal regulations. The PureWick™ Urine Collection System (PW100 and PW200) contains electrical and/or electronic equipment, and the PW200 product contains a lithium-ion battery that must be disposed of per local laws and regulations.

Transporting the PureWick™ Urine Collection System (PW200 only):

The PureWick™ Urine Collection System with battery contains a lithium-ion battery which is considered a hazardous material. Transporting it is governed by federal and local laws.

Specifications (PW100 and PW200)

Class II
Type BF Applied Part (the collector tubing is the applied part)
IP21
Operating suction range: Approximately 120 mmHg – 140 mmHg (2.3 – 2.7 psi)
Maximum suction level: 182 mmHg (3.5 psi)

Electrical Specifications

AC input voltage: 100 –240VAC
AC frequency: 50 – 60Hz 10A
AC connector: NEMA 1-15P

Environmental Specifications

	PW100	PW200
Operating Temperature Limit	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)
Storage Temperature Limit	-13°F–158°F (-25°C–70°C)	-13°F–104°F (-25°C–40°C)
Transport Temperature Limit	-13°F–158°F (-25°C–70°C)	-13°F–158°F (-25°C–70°C)
Humidity Limitation	5 –90%, non-condensing	5 –90%, non-condensing
Operating Atmospheric Pressure Limitation	70 kPa - 106 kPa	70 kPa - 106 kPa
Storage/Transport Atmospheric Pressure Limitation	50 kPa - 106 kPa	50 kPa - 106 kPa

When the PureWick™ Urine Collection System has been stored in a very cold environment (down to -13°F or -25°C), please allow the device to sit for approximately 90 minutes at room temperature (approximately 68°F or 20°C) before use.

When the PureWick™ Urine Collection System has been stored in a very warm environment (up to 158°F or 70°C), please allow the device to sit for approximately 90 minutes at room temperature (approximately 68°F or 20°C) before use.

Physical Specifications

Dimensions with canister: 9” x 6.5” x 11” (22.86cm x 16.51cm x 27.94cm)
Dimensions without canister: 8.75” x 6” x 7.5” (22.22cm x 15.24cm x 19.05cm)
Cord length: 12’ (3.65m)

Battery Specifications (PW200 only)

Battery: Lithium-ion battery
Charging Time: 12 hours

PureWick™ Urine Collection System Limited Product Warranty

C. R. Bard, Inc., warrants to you, the original purchaser of this product, that this product (but not its battery if one is included) will be free from defects in material and workmanship for a period of three (3) years from your date of purchase. For the purposes of this warranty, the original purchaser of this product is the first purchaser of this product from C. R. Bard, Inc. or an authorized retailer. Any limited warranties are not transferable.

The liability of C. R. Bard, Inc. under this limited product warranty will be limited, at its option, to replacement or repair of the defective product, or to refund your net price paid at C. R. Bard, Inc.'s discretion.

For all warranty issues, please call 1-888-201-1586 Monday – Friday from 9:00 AM to 5:00 PM EST. Before receiving warranty service, C. R. Bard may require that you furnish proof of purchase details and respond to questions designed to assist with diagnosing potential issues for obtaining warranty service.

If the product proves to be defective, C. R. Bard will send you prepaid packaging so that you may ship your defective PureWick™ Urine Collection System back to the manufacturer. C. R. Bard will replace and ship your new PureWick™ Urine Collection System back to you within 90 days of receiving your defective equipment. A replaced PureWick™ Urine Collection System is subject to the same limited warranty as the original device.

Wear and tear from normal use or defects resulting from any abuse, misuse, improper storage, alteration, further manufacture, packaging, or processing of this product are not covered by this limited warranty.

This limited warranty does NOT cover any loss of functionality of the battery (if one is included), including a battery which no longer holds a charge, or the perceived slowness of charging.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES RESPECTING THIS PRODUCT, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANY IMPLIED WARRANTIES REQUIRED BY APPLICABLE LAW ARE LIMITED IN DURATION TO THE THREE (3) YEARS TERM OF THIS LIMITED WARRANTY.

IN NO EVENT WILL C. R. BARD, INC. BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES UNDER THIS WARRANTY.

C. R. Bard, Inc.'s total liability will not exceed the purchase price paid for the PureWick™ Urine Collection System. In no event will C. R. Bard, Inc. be liable for procurement of substitute products.

Some states do not allow an exclusion or limitation of implied warranties, incidental or consequential damages, so the above limitation may not apply to you. You may be entitled to additional remedies under state law.

If you have any questions regarding how to use your PureWick™ Urine Collection System, please contact 1-888-201-1586.

Guidance and Manufacturer's Declarations

Table 1: Electromagnetic emissions	
This equipment is intended for use in the electromagnetic environment specified below. The user of the equipment should assure that it is used in such an environment	
Emissions Test	**Compliance**
RF emissions *CISPR 11*	Complies Group 1
RF emissions *CISPR 11*	Complies Class B
Harmonic emissions *IEC 61000-3-2*	Complies Class A
Voltage fluctuations / flicker emissions *IEC 61000-3-3*	Complies

Table 2: Electromagnetic immunity		
This equipment is intended for use in the electromagnetic environment specified below. The user of the equipment should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge IEC 61000-4-2	+ 8 kV Contact, HCP & VCP +2 kV, +4 kV, +8 kV, + 15 kV Air	+ 8 kV Contact, HCP & VCP +2 kV, +4 kV, +8 kV, + 15 kV Air
Radiated RF Immunity IEC 61000-4-3	80 MHz - 2.7 GHz, 10 V/m, 80% 1 kHz AM	80 MHz - 2.7 GHz, 10 V/m, 80% 1 kHz AM
Electrical Fast Transient/Burst IEC 61000-4-4	+ 2 kV (100 kHz rep rate) AC mains + 1 kV (100 kHz rep rate) I/O > 3m	+ 2 kV (100 kHz rep rate) AC mains + 1 kV (100 kHz rep rate) I/O > 3m
Surge Immunity IEC 61000-4-5	+0.5 kV & + 1 kV line-line, AC mains	+0.5 kV & + 1 kV line-line, AC mains
Conducted RF immunity IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency H-field IEC 61000-4-8	50 and 60 Hz, 30 A/m, x-, y-, and z- axes	50 and 60 Hz, 30 A/m, x-, y-, and z- axes

Voltage Dips, Interrupts IEC 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle
Proximity magnetic fields IEC 61000-4-39	8 A/m, CW Modulation @ 30kHZ 65 A/m, 2.1 kHz Pulse Modulation @134.2kHz 7.5 A/m, 50 kHz Pulse Modulation @13.56MHz	8 A/m, CW Modulation @ 30kHZ 65 A/m, 2.1 kHz Pulse Modulation @134.2kHz 7.5 A/m, 50 kHz Pulse Modulation @13.56MHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3: Complies, refer below IEC 60601-1-2: Table 9 (please refer the below table in page 16).		

IEC 60601-1-2: Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				

The PureWick™ Urine Collection System bears the following symbols:

Packaging Unit	Non-sterile	Class II	Humidity Limitation
REF Catalog Number	Do not use if package is damaged and consult Instructions for Use.	Type BF Applied Part	Atmospheric Pressure Limitation
LOT Lot Number	Caution	Refer to Instruction Manual/ Booklet	Caution, Risk of Electric Shock
SN Serial Number	Manufacturer	Temperature Limit	IP21 Degree of Protection against harmful ingress of water and particulate matter.
Use By date	Date of Manufacture	ETL CLASSIFIED c ETL us Intertek 5025215 M.E.E. Certified To CSA STD C22.2 NO. 60601-1 Conforms To Medical Electrical Equipment STDS 60601-1, 60601-1-6 and 60601-1-11	

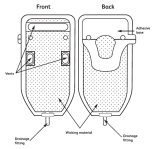
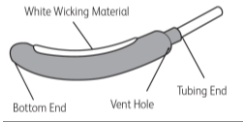
⚠ **WARNING:** This product[1] can expose you to lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to: https://www.P65Warnings.ca.gov.

[1] The product is the A/C Power Cord.

IP21 Classification – Protection of equipment against ingress of solid foreign objects which are greater than or equal to 12.5mm in diameter and protection of equipment against harmful effects of ingress from vertically dripping water.

Template GFM-10095B

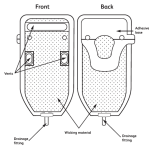
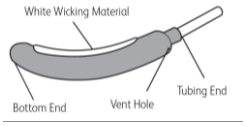
26.4 Appendix 4 - Participant - Perception of Wetness Questionnaire (**Both Male & Female**)

Participant Number:	Device:  PureWick Male External Catheter  PureWick Flex Female External Catheter

After HCP Placement Void						
		Extremely wet	Very wet	Somewhat wet	Slightly wet but acceptably dry	Dry (not at all wet)
	Question	**1**	**2**	**3**	**4**	**5**
1	On a scale of 1-5 where 1 is 'Extremely wet' and 5 is 'Dry, (not at all wet)', how wet or dry did you feel after your urination (pee)?					
1a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text)					
	Question	**Yes**	**No**			
2	Did you feel leakage while urinating during use of the device?					

After Self-Placement Void						
		Extremely wet	Very wet	Somewhat wet	Slightly wet but acceptably dry	Dry (not at all wet)
	Question	**1**	**2**	**3**	**4**	**5**
1	On a scale of 1-5 where 1 is 'Extremely wet' and 5 is 'Dry, (not at all wet)', how wet or dry did you feel after your urination (pee)?					
1a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text)					
	Question	**Yes**	**No**			
2	Did you feel leakage while urinating during use of the device?					

26.5 Appendix 5 – Participant – Ease of use Questionnaire (**Both Male & Female)**

Participant Number:	Device:  PureWick Male External Catheter  PureWick Flex Female External Catheter

After Self-Placement Void

		Very difficult	Somewh at difficult	Average difficulty	Somewh at easy	Very easy
	Question	**1**	**2**	**3**	**4**	**5**
1	On a scale of 1-5, where 1 is Very difficult, and 5 is Very Easy, How easy was the **placement** of the device?					
2	On a scale of 1-5, where 1 is Very difficult, and 5 is Very Easy, How easy was the **removal** of the device?					

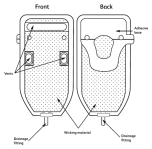
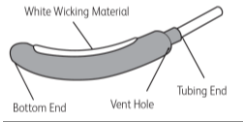
****The following questions are applicable for FEMALE participants only.****

Please respond to the following questions regarding the PureWick™ Flex Female External Catheter on a scale of 1-5, where 1 is Strongly Disagree, and 5 is Strongly Agree.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	Question	**1**	**2**	**3**	**4**	**5**
3	I was able to connect the device PureWick™ Flex FEC tubing to the suction tubing on the PureWick™ Urine Collection System					
3a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					
4	I was able to locate the vent hole on the PureWick™ Flex FEC and make sure it was not blocked.					
4a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					

5	I would be able to tell if the PureWick™ Flex FEC came out of place.					
5a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					
6	I would be able to tell if the PureWick™ Flex FEC was in the correct orientation (i.e. tubing pointed toward the belly button).					
6a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					
7	I was able to curve the PureWick™ Flex FEC to fit my body.					
7a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					

26.6 Appendix 6 – Participant Comfort Questionnaire (**Both Male and Female**)

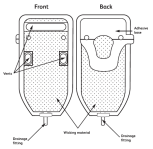
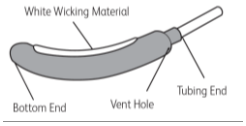
Participant Number:	Device:
	 PureWick Male External Catheter  PureWick Flex Female External Catheter

After Completion of All Voids

Please respond to the following questions regarding device comfort on a scale of 1-5, where 1 is Very Uncomfortable, and 5 is Very Comfortable

		Very uncomfortable	Uncomfortable	Neither Comfortable nor Uncomfortable	Comfortable	Very Comfortable
	Question	**1**	**2**	**3**	**4**	**5**
1	How comfortable was the **placement** of the PureWick™ External Catheter?					
2	How comfortable was the device while you were **voiding**?					
3	How comfortable was the **removal** of the PureWick™ External Catheter?					
		Very Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Very Likely
	Question	**1**	**2**	**3**	**4**	**5**
4	On a scale of 1 to 5 where 1 is very unlikely and 5 is very likely, how likely would you be to recommend the PureWick™ External Catheter to someone else?					

26.7 Appendix 7 – Participant IFU Evaluation Questionnaire (**Both Male and Female)**

Participant Number:	Device:  PureWick Male External Catheter  PureWick Flex Female External Catheter

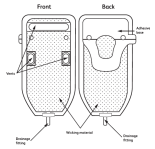
After Self-Placement Void

Please respond to the following questions regarding the PureWick™ External Catheter on a scale of 1-5, where 1 is Strongly Disagree, and 5 is Strongly Agree.

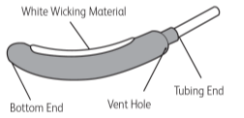
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	Questions	**1**	**2**	**3**	**4**	**5**
1	I was able to understand and follow the written instructions in the PureWick™ External Catheter instructions for use so that I could perform the steps myself.					
1a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					
2	I was able to understand the pictures in the PureWick™ External Catheter instructions for use so that I could perform the steps myself.					
2a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					
3	I was able to place the PureWick™ external catheter on myself.					
3a	If you selected 1, 2 or 3, please provide comments to tell us why you answered as you did (free text).					

26.8 Appendix 8 – HCP – Ease of use Questionnaire

HCP Initials:	Device:



PureWick Male External Catheter



PureWick Flex Female External Catheter

PUREWICK™ MALE - After Completion of All Participants

		Very Difficult	Somewhat Difficult	Average Difficulty	Somewhat Easy	Very Easy
	Question	**1**	**2**	**3**	**4**	**5**
1	On a scale of 1 to 5 where 1 is very difficult and 5 is very easy, how easy was the placement of the device?					
2	On a scale of 1 to 5 where 1 is very difficult and 5 is very easy, how easy was the removal of the device?					

PUREWICK™ FEMALE - After Completion of All Participants

		Very Difficult	Somewhat Difficult	Average Difficulty	Somewhat Easy	Very Easy
	Question	**1**	**2**	**3**	**4**	**5**
1	On a scale of 1 to 5 where 1 is very difficult and 5 is very easy, how easy was the placement of the device?					
2	On a scale of 1 to 5 where 1 is very difficult and 5 is very easy, how easy was the removal of the device?					

Signature Page for VV-TMF-314928 v1.0

Reason for signing: Finalize	Name: Ajesh Raju Role: Clinical Project Management Date of signature: 09-Aug-2024 17:15:47 GMT+0000
Reason for signing: Finalize	Name: Kirsten Hammitt Role: Clinical Safety Management Date of signature: 09-Aug-2024 17:28:09 GMT+0000
Reason for signing: Finalize	Name: Amy Lewis Role: Legal Date of signature: 09-Aug-2024 17:36:53 GMT+0000
Reason for signing: Finalize	Name: Anvitha Karne Role: Clinical Data Manager Date of signature: 09-Aug-2024 18:15:19 GMT+0000
Reason for signing: Finalize	Name: Gerald Denny Role: Medical Affairs Core Team Member Date of signature: 09-Aug-2024 19:06:09 GMT+0000
Reason for signing: Finalize	Name: Bhawankumar Patel Role: Clinical Quality and Compliance Date of signature: 09-Aug-2024 19:58:02 GMT+0000
Reason for signing: Finalize	Name: Shujie (Susie) Xiao Role: Clinical Statistician Date of signature: 09-Aug-2024 20:02:07 GMT+0000

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