Protocol Number: UCC-23AC022 CONFIDENTIAL

Version:1.0

Date: 16May2023

TITLE PAGE

Protocol Title:

Evaluating the efficacy and comfort of the PureWick™ Male External Catheter against a Comparator in Healthy Volunteers

Protocol Number: UCC-23AC022

Version Number: 1.0

Study Device: BD PureWick™ Male External Catheter (PWM030)

Study Type: Post-Market

Short Title: MECCE (Male External Catheters' Comparison of Comfort & Efficacy)

Sponsor Name: Becton, Dickinson and Company

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Regulatory Agency Identifier Number(s): NCT number TBD

National Principal Investigator: TBD

Version History

Version Number	Date	Type
1.0	TBD	Original

SPONSOR PROTOCOL APPROVAL

Signature below indicates approval of the protocol as written.			
Individual or function	**Name**	**Signature**	**Date**
Medical Affairs Team Representative	Danielle Redmond	*This document is signed electronically in the eTMF system*	
Study Statistician	Yanchang Zhang	*This document is signed electronically in the eTMF system*	
Regulatory Affairs	Jenny McKinnon	*This document is signed electronically in the eTMF system*	
Clinical Affairs	Kirsten Hammitt	*This document is signed electronically in the eTMF system*	
UCC – Quality Engineering	Michael Wolfe	*This document is signed electronically in the eTMF system*	

PROTOCOL SIGNATURE PAGE

Investigator Responsibilities

1. Prior to participation in this study, the Investigator or Institution must sign the Clinical Study Agreement (CSA) and obtain written approval from the appropriate Institutional Review Board (IRB)/Ethics Committee (EC).
2. The Investigator must receive BD-sponsored training prior to site activation. The Investigator is responsible for ensuring that all Sub-Investigators and clinical staff are adequately trained prior to performing any data collection or study-related procedures.
3. The Principal Investigator shall ensure that the study is conducted in accordance with the study protocol, any modifications as requested by the IRB/EC, the signed CSA, the ethical principles of the Declaration of Helsinki, Good Clinical Practice (ICH E6) / ISO 14155), and applicable national/regional regulations and laws.
4. If applicable, ensure that written informed consent is obtained from each participant prior to the conduct of any study procedure, using the current IRB/EC approved Informed Consent Form.

I have read and understand the contents of this study protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the trial in accordance with the study protocol, the signed Clinical Study Agreement, and Good Clinical Practice (GCP) as well as applicable FDA and ISO regulations (e.g., 21 CFR Parts 812, 50, 54, 56; ISO 14155). I agree to participate in BD-Sponsored training prior to performing any data collection or study-related procedures.

Agreed to by (Investigator):

_____

Printed Name – Investigator

_____

Signature – Investigator

_____

Site Number

_____

Date

Abbreviations

AE	Adverse event
Bard	C. R. Bard, Inc.
BD	Becton Dickinson and Company
BMI	Body Mass Index
CFR	Code of Federal Regulations
CI	Confidence Interval
CRF	Case Report/Record Form
CRO	Contract Research Organization
EDC	Electronic Data Capture
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act of 2007
GCP	Good Clinical Practice
HCP	Health Care Professional
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IFU	Instructions for use
IRB/EC	Institutional or Independent Review Board/Ethics Committee
MEC	Male external catheter
SAE	Serious Adverse Event
SD	Standard Deviation
SoA	Schedule of Activities
SOP	Standard Operating Procedure
TMF	Trial Master File
WHO	World Health Organization

1 PROTOCOL SUMMARY

1.1 Synopsis

Protocol Title	Evaluating the efficacy and comfort of the PureWick™ male external catheter against a comparator in Healthy Volunteers	
Short Title	MECCE (Male External Catheters' Comparison of Comfort & Efficacy)	
Rationale	The purpose of this study is to provide clinical evidence to compare the effectiveness and comfort of PureWick™ Male against a comparator for non-invasive urine output management in patients with varying male anatomy.	
Objectives and Endpoints	Objective(s)	Endpoint(s)
	Primary • To assess the performance of the PureWick™ Male (System) against an established comparator (Stryker/ Sage PrimoFit™)	Primary • Capture rate following void (captured as % of urine captured by device and collected in canister, measured by weight)

Protocol Title	Evaluating the efficacy and comfort of the PureWick™ male external catheter against a comparator in Healthy Volunteers	
	Secondary Objective (with Hypothesis Test): • To assess the performance of the PureWick™ Male (System) in patients that are unable to use traditional sheath style condom catheters. Secondary Objective (without Hypothesis test): • To assess participant comfort after using the MEC • To assess ease of use by HCP in placing the MEC	Secondary • Capture rate following void (captured as % of urine captured by device and collected in canister, measured by weight). • Overall Comfort score on a 5-point Likert scale (brief questionnaire) • Ease of use score on a 5-point Likert scale (brief questionnaire)
Design and Overview	This is a Prospective, Randomized, Crossover, Single-blind, Single Center Healthy Volunteer Study conducted over 1 day, with 2 voids using the PW Male external catheter vs. comparator Sage PrimoFit™. This study is designed to assess the performance, comfort, and ease of use of the PW Male external catheter as compared to the comparator product.	

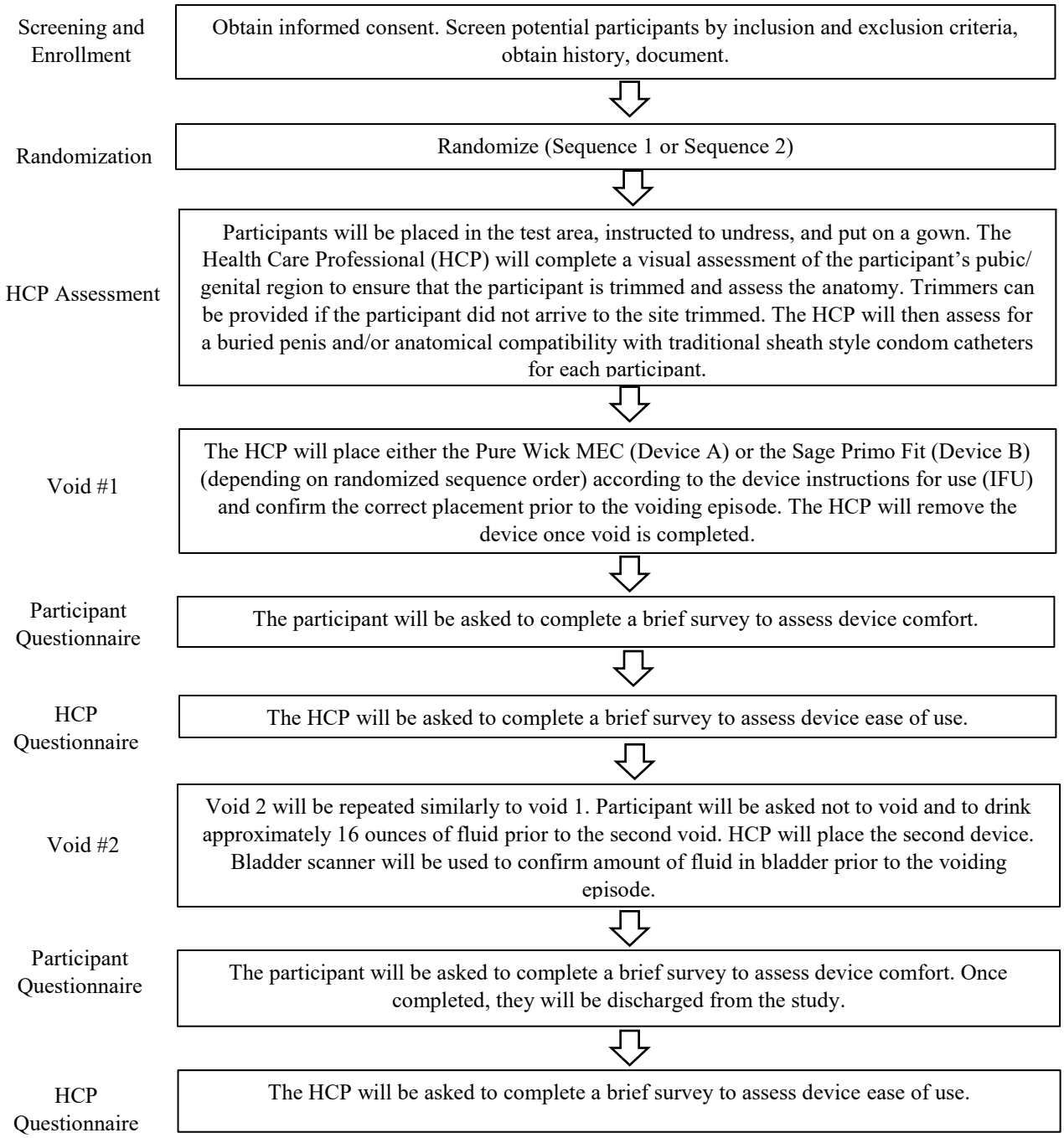
Protocol Title	Evaluating the efficacy and comfort of the PureWick™ male external catheter against a comparator in Healthy Volunteers
Study Device	**Test product(s):** BD PureWick™ Male (PWM030) The PureWick™ Male External Catheter (MEC) is intended for non-invasive urine output management in male patients. The PureWick™ Male External Catheter is a commercially available device which is Class I, 510(K) exempt. **Reference/Comparator product(s):** Sage PrimoFit™ (5404) The Sage PrimoFit™ is a commercially available device which is Class I, 510(K) exempt. **Ancillary Product(s):** • Standard suction tubing and cannister • BBS Revolution: Bladder Scanner + Display (PD0100002) • Absorbent under-pads • Commercially available scales • Clippers/trimmers • Wipes/towels for peri-care • Turning wedge (45-degree foam wedge) • PPE

Protocol Title	Evaluating the efficacy and comfort of the PureWick™ male external catheter against a comparator in Healthy Volunteers
Participants	Adult male healthy volunteers with a target of 50% of subjects in each of the following cohorts: o Cohort A: Non morbidly obese men: BMI <40 o Cohort B: Morbidly Obese men: BMI ≥40 o Inclusion Criteria: • Adult Male Patients ≥18 years old • Male anatomy at time of enrollment • Ability to speak and understand English • Willing to comply with all study procedures in this protocol • Able to independently void urine • Provision of signed and dated informed consent form Exclusion Criteria: • Urinary incontinence which does not allow the subject to spontaneously void • Frequent episodes of bowel incontinence • Has Urinary Retention • Has any irritation, wound, open lesion, at the application site, on the genitalia, perineum, or sacrum • Recent surgery of the external urogenital tract, penis, or pubic area • Not able to comply with study procedures independently without required assistance • Any other condition that, in the opinion of the investigator, would preclude them from participating in the study

Intervention(s)/Procedure(s)	Prior to arrival, participants will be instructed to consume fluids and to come to the test site with a full bladder. Upon arrival at the test site, participants will be consented and screened against inclusion/exclusion criteria. Those meeting eligibility criteria will be assigned a treatment order. Participants will be divided into two cohorts. Cohort A: Non morbidly obese men: BMI <40 Cohort B: Morbidly obese men: BMI ≥40 Participants will be placed in the test area, instructed to undress, and put on a gown. The Health Care Professional (HCP) will complete a visual assessment of the participant's pubic/ genital region to ensure that the participant is trimmed and assess the anatomy. Trimmers can be provided if the participant did not arrive to the site trimmed. The HCP will then assess for a buried penis and/or anatomical compatibility with traditional sheath style condom catheters for each participant. "A buried penis refers to a normal-sized phallus encompassed by either skin, subcutaneous tissue, and/or fat in the prepubic area" causing a reduced visible and/or functional length of the phallus.[11] Void 1: The bed in the test area will be set with a pre-weighed absorbent pad and a pre-weighed urine collection canister (with the lid). Once the participant feels the need to void, the Health Care Professional (HCP) will place either the PureWick™ MEC (Device A) or the Sage PrimoFit™ (Device B) (depending on randomized treatment order) according to the device instructions for use (IFU) and confirm the correct placement prior to the voiding episode. The participant will be placed in a semi-fowler position (head of bed elevated approximately 30 degrees) in a hospital bed and turned to one side using a turning wedge prior to the voiding episode. Participants will be monitored for approximately 2 hours from the time of the device application, through one void. (The skin needs to be assessed at least every two hours while wearing a MEC.) After the void, the pre-weighed absorbent pad and urine collection canister will be weighed (with the lid), and weights documented in the source. The Pure Wick MEC or Sage PrimoFit™ will be removed by the HCP. After removal, the HCP will note any signs of irritation/injury in the perineal area. Any unresolved erythema (redness), erythema (swelling), bleeding, injury, or rash should be recorded as an Adverse Event.

Protocol Title	Evaluating the efficacy and comfort of the PureWick™ male external catheter against a comparator in Healthy Volunteers
	The participant will be asked to complete a brief survey to assess device comfort immediately after the completed void. The HCP will be asked to complete a brief survey to assess device ease of use for the participant just treated. Void 2: Participants will be asked to not void and to drink approximately 16 fluid ounces of liquid. When the participant feels the need to void (a second time), the HCP will confirm via bladder scanning procedure that the bladder volume is ≥125mL If the volume is determined to be inadequate, the participant will be asked if they can wait to void, drink additional fluids as tolerated and be re-assessed in approximately 30 minutes. If the participant does not feel comfortable waiting to void, they will be allowed to proceed with void 2. Void 2 will be repeated per the Void 1 procedure using the 2nd device assigned per randomization. The participant will complete a brief survey (for the second device sequence) immediately following the void to assess device comfort and will then be discharged from the study. The HCP will complete a brief survey to assess device ease of use for the participant just treated.
Investigational Sites	1 site in the US
Data Monitoring Committee	Not Applicable
Regulatory Status	Post-Market The investigation will use both the PureWick™ Male External Catheter and Sage PrimoFit™ for its intended purpose.

1.2 Schema



2 INTRODUCTION

The PureWick™ MEC is intended for non-invasive urine output management in male patients. The PureWick™ MEC is a single use nonsterile device. It is composed of the following elements: a flexible polyurethane shell, a patient-contacting adhesive intended for up to 24 hours of wear, a spacer fabric layer to function as a fluid pathway, a drainage fitting to connect to standard hospital suction, and vents to allow for air intake. To capture voided urine, the catheter is connected to a wall vacuum system. This vacuum (not felt by the user) is intended to pull urine through the catheter, regardless of the urine flow rate. Urine continues quickly through vinyl tubing until it reaches a collection canister, away from the body.

The PureWick™ MEC does not require a doctor's order, is a commercially available and marketed device commonly used in the hospital setting, and is an FDA 510(k) Exempt, Class I device. See Appendix 1 for the Instructions for Use (IFU).

2.1 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] Lastly, condom catheters can only be used for males with normal anatomy and cannot be used with men with buried/hidden penis. “A buried penis refers to a normal-sized phallus encompassed by either skin, subcutaneous tissue, and/or fat in the prepubic area” causing a reduced visible and/or functional length of the phallus[11]; buried penis is an acquired deformity secondary to obesity[8,9]. Obesity is increasing in our society, with a prevalence of up to 40.8% in middle-aged men.[8] This condition is also commonly seen in the acute care setting in critically ill patients with third spacing and generalized gross edema. Although no published data are available that could be found regarding the specific incidence of the hidden penis in morbidly obese men, acquired buried penis is increasing in incidence in adult men as morbid obesity becomes more prevalent.[10]

The PureWick™ Male External Catheter (MEC) is a new external drainage device to address the need for an effective, non-invasive method of managing urine output in male patients.

2.2 Rationale

The purpose of this study is to provide clinical evidence to compare the effectiveness and comfort of PureWick™ Male against a comparator for non-invasive urine output management in patients with varying male anatomy. Specifically, the study will collect data about how the male external catheters perform when participants are positioned on their side using a turning wedge with the head of the bed elevated, mimicking common patient positioning in the hospital setting.

2.3 Risk/Benefit Assessment

Participants in this study will be treated with approved, marketed devices and will use the investigational devices as intended. Therefore, participants will be exposed to the same risks shared by all patients using these devices for urine output management in a real-world setting. More detailed information about the known and expected benefits and risks and reasonably expected adverse events of the PureWick™ MEC and the Sage PrimoFit™ may be found in the Instructions for Use of each product.

2.3.1 Risk Assessment

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
Study Intervention: PureWick™ Male External Catheter		
Potential adverse events: • Skin injury • Skin irritation • Allergic reaction	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.
Study Intervention: Sage PrimoFit™		
Potential adverse events: • Skin injury • Skin irritation	Sage PrimoFit™ is an external urine management device for the male anatomy that adheres to the pelvic and abdominal skin.	• Clean, prep, and dry patient's genital area before device application • Perform skin assessment every 2 hours

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
		• Assess device periodically to ensure proper placement, particularly after turning or repositioning patient. • Device can be left on skin for up to 24 hours. Replace device if soiled with stool or bodily fluids other than urine. • Discontinue use during patient ambulation.
Study Procedures		
Discomfort due to full bladder	Participants will be asked to refrain from voiding until bladder volume reaches ≥125mL 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.

2.3.2 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 PureWick™ MEC or Sage PrimoFit™. 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 patients.

2.3.3 Overall Benefit: Risk Conclusion

Taking into consideration the measures to minimize risk to participants in this study, the potential risks identified in association with both the PureWick™ Male External Catheter and the Sage PrimoFit™ are minimal. Both products are commercially available for use. This is a post-market, non-significant risk study.

3 OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
• To assess the performance of the PureWick™ Male (System) against an established comparator (Stryker/ Sage PrimoFit™)	• Capture rate following void (captured as % of urine captured by device and collected in canister, measured by weight)
Secondary (With Hypothesis Test)	
• To assess the performance of the PureWick™ Male (System) in patients that are unable to use traditional sheath style condom catheters	• Capture rate following void (captured as % of urine captured by device and collected in canister, measured by weight)
Secondary (Without Hypothesis Test)	
• To assess participant comfort after using the MEC	• Overall Comfort score on a 5-point Likert scale (brief questionnaire)
• To assess ease of use by HCP in placing and removing the MEC	• Ease of use score on a 5-point Likert scale (brief questionnaire)

4 STUDY DESIGN

4.1 Overall Design

In this prospective, post-market, crossover, single-blind, single center healthy volunteer study, healthy males will be randomized 1:1 to a treatment sequence using two devices

(PureWick™ Male External Catheter and Sage PrimoFit™) and followed for 1 day through 2 voids. Approximately 50 participants will be enrolled in this study to obtain 44 evaluable subjects. This study is designed to assess the performance, comfort, and ease of use of the PW Male external catheter.

Prior to arrival, participants will be instructed to consume fluids and to come to the study site with a full bladder. Upon arrival at the site, participants will be consented and screened against inclusion/exclusion criteria. Participants meeting eligibility criteria will be assigned a treatment cohort. Participants will be divided into two cohorts.

A. Non-morbidly obese men: BMI <40 or;
B. Morbidly Obese men: BMI ≥40.

Prior to any study activities, participants will be asked to review the Informed Consent Form and will have an opportunity to ask the Principal Investigator (PI) any questions. Participants will be considered enrolled after the PI determines they meet the inclusion criteria and receive a signed copy of the Informed Consent Form.

Participants will be placed in the test area, instructed to undress, and put on a gown. The Health Care Professional (HCP) will complete a visual assessment of the participant's pubic/ genital region to ensure that the participant is trimmed and assess the anatomy. Trimmers can be provided if the participant did not arrive to the site trimmed. The HCP will assess for a buried penis and/or anatomical compatibility with traditional sheath style condom catheters for each participant. "A buried penis refers to a normal-sized phallus encompassed by either skin, subcutaneous tissue, and/or fat in the prepubic area" causing a reduced visible and/or functional length of the phallus.[11]

Void 1:

The bed in the test area will be set with a pre-weighed absorbent pad and a pre-weighed urine collection canister (with the lid). Once the participant feels the need to void, the Health Care Professional (HCP) will place either the PureWick™ MEC or the Sage PrimoFit™ device (depending on randomized treatment order) according to the device instructions for use (IFU) and confirm the correct placement prior to the voiding episode. The participant will be placed in a semi-fowler position (head of bed elevated approximately 30 degrees) in a hospital bed and turned to one side using a turning wedge prior to the voiding episode. Participants will be monitored for approximately 2 hours from the time of the device application, through one void. The skin needs to be assessed at least every two hours while wearing a MEC. After the void, the pre-weighed absorbent pad and urine collection canister will be weighed (with the lid), and weights documented in the source. The Pure Wick MEC or Sage PrimoFit™ will be removed by the HCP. After removal, the HCP will note any signs of irritation/injury in the perineal area. Any

unresolved erythema (redness), erythema (swelling), bleeding, injury, or rash should be recorded as an Adverse Event. The participant will be asked to complete a brief survey to assess device comfort immediately after the completed void.

The HCP will complete a brief survey to assess device ease of use for the participant just treated.

Void 2:

Participants will be asked to not void and to drink approximately 16 fluid ounces of liquid. When the participant feels the need to void (a second time), the HCP will confirm via bladder scanning procedure that the bladder volume is ≥125mL. If the volume is determined to be inadequate, the participant will be asked to drink fluids as tolerated and re-assessed in approximately 30-60 minutes.

Void 2 will be repeated per the Void 1 procedure using the 2nd device assigned per randomization.

The participant will be asked to complete a brief survey (for the second device sequence) immediately following the void to assess device comfort and will then be discharged from the study.

The HCP will complete a brief survey to assess device ease of use for the participant just treated.

4.2 Scientific Rationale for Study Design

This study will assess the performance of and user experience with PureWick™ Male External Catheter when compared with a marketed comparator, Sage PrimoFit™ Male External Catheter. To best mimic potential users of the study devices, male participants ≥18 years of age will be enrolled. Additionally, enrollment will target approximately 50% of the sample size of men in two different BMI cohorts so that potential differences based on anatomy can be characterized. As such, participants in this study adequately represent the patients who would use the device in the hospital setting.

In the critical care setting or with patients that have limited mobility, it is commonly ordered for patients to be repositioned and turned on their side every two hours. A turning wedge is a device used by hospitals to prop the patient onto their side. Additionally, the patient is commonly ordered to elevate the head of the bed. The Primary endpoint provides a reliable and valid measurement of the efficacy related to the function of the device by capturing and weighing all urine output per void, including leakage, and dividing by the captured amount of urine in the canister. A higher captured rate constitutes a more meaningful effect. Questionnaires using a 5-point Likert scale will be administered to each participant to assess comfort, and to each HCP to assess ease of use. A higher Likert score, such as a 4 or 5, constitutes a more meaningful effect on these

secondary endpoints. Furthermore, this study seeks to understand if the PureWick™ MEC will perform effectively in male anatomy that is not compatible with traditional sheath-style condom catheters in a controlled setting.

4.2.1 Participant Input into Design

There was no participant involvement in the design of this study.

4.3 End of Study Definition

A participant is considered to have completed the study if he has completed both voids and the corresponding questionnaires.

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

5 STUDY POPULATION

Adult male healthy volunteers will be recruited for this study with a target of 50% of participants in each of the two BMI cohorts. Participants will be recruited from an existing pool of volunteers in a database owned by a third-party research vendor. Basic screening questions will be used to identify potential participants and full screening against inclusion/exclusion criteria will be completed on the day of enrollment.

5.1 Inclusion Criteria

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

1. Adult Male Patient ≥ 18 years old
2. Male anatomy at time of enrollment
3. Ability to speak and understand English
4. Willing to comply with all study procedures in this protocol
5. Able to independently void urine
6. Provision of signed and dated informed consent form

5.2 Exclusion Criteria

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

1. Urinary incontinence which does not allow the subject to spontaneously void
2. Frequent episodes of bowel incontinence
3. Has Urinary Retention
4. Has any irritation, wound, open lesion, at the application site, on the genitalia, perineum, or sacrum
5. Recent surgery of the external urogenital tract, penis, or pubic area
6. Not able to comply with study procedures independently without required assistance
7. Any other condition that, in the opinion of the investigator, would preclude them from participating in the study

5.3 Lifestyle Considerations

No restrictions are required.

5.4 Screen Failures

Screen failures are defined as participants 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.

6 STUDY INTERVENTION(S)

6.1 Investigational/Test Device

The PureWick™ MEC is a commercially available device. It is a Class I, 510(k) exempt device. The device is intended for non-invasive urine output management in male patients. The PureWick™ MEC is a single-use, non-sterile device. The IFU for the PureWick™ MEC can be found in Appendix 1.

6.2 Control Device/Standard of Care

The Sage PrimoFit™ is a commercially available device. It is a Class I, 510(K) exempt device. The device is intended for non-invasive external collection of urine for adult

patients with male anatomy who require urine management. The Sage PrimoFit™ is a single -use, non-sterile device. The IFU for the Sage PrimoFit™ can be found in Appendix 2.

6.3 Ancillary Devices/Products

Ancillary products for this study are listed below.

- Standard suction tubing and canisters
- BBS Revolution: Bladder Scanner + Display (PD0100002)
- Absorbent under-pads
- Commercially available scales
- Clippers/trimmers
- Wipes/towels for peri-care
- Turning wedge (45-degree foam wedge)
- PPE

6.4 Device Labeling

All commercial products will be supplied as labeled by the manufacturer. The study site will document all study devices and products received.

6.5 Treatment Allocation and Measures to Minimize Bias

Known foreseeable factors that could potentially compromise the outcome of the investigation or interpretation of the results or introduce bias into the study are delineated in this section.

This is a single-blind, cross-over study in which each subject acts as his own control and therefore, the difference in treatments is derived from a within-subject comparison. This allows for better control of potential cofounders and removes the inter-subject variability from the comparison between treatment groups.

Standardized questionnaires will be used to assess participant comfort and HCP ease of use. As training level and device experience could be a foreseeable factor that could impact ease of use outcomes, HCPs will all be trained using standardized instructional videos and device IFUs.

6.5.1 Randomization

Participants will be randomized 1:1 to one of the two treatment sequences. Subjects randomized to Sequence 1 will use PureWick™ MEC first, followed by

Sage PrimoFit™. Subjects randomized to Sequence 2 will use Sage PrimoFit™ first, followed by PureWick™ MEC. Randomization will be stratified by cohorts (non-morbidly obese men: BMI <40 or morbidly obese men: BMI ≥40). This design allows for the evaluation of elements such as carryover effect, period effect, and sequence effect.

The study site will receive randomization envelopes for each cohort that are numbered in sequential order. Within each randomization envelope, a treatment sequence assignment card will be enclosed. The randomization envelopes should be opened in sequential order only when all eligibility criteria are met.

6.5.2 Blinding/Masking

Complete study blinding is not feasible due to possible HCP familiarity with the study devices and visual differences between the product packaging. As such, this is a single-blind study in which only participants are blinded to which device is which. The Investigator and Sponsor will know which device the participant is being treated with at any given time.

Blinding procedures will be reviewed at the time of site initiation by a Sponsor representative. During review of the study and the informed consent process with participants, blinding and rationale should be discussed with the participant.

Any communication to the study personnel placing the device as to the randomized treatment sequence should be done in a way as to prevent the participant from overhearing. Devices should be referred to throughout the study period as ‘Device A’ and ‘Device B’ rather than the marketed product name.

Participants will remain blinded to treatment order until the study is complete.

7 STUDY PROCEDURES AND ASSESSMENTS

Study procedures and their timing are summarized in section 1.2. Protocol waivers or exemptions are not allowed. Adherence to the study design requirements, including those specified in this protocol, 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.

7.1 Subject Preparation – Prior to Arrival at Site

Participants will be instructed to consume fluids prior to their scheduled visit and arrive to the site with a full bladder. Participants will be instructed to trim the hair in their pubis/ peri-area prior to arrival.

7.2 Screening and Enrollment

All participants will be screened against the inclusion and exclusion criteria (see section 5.1 & 5.2). Eligibility criteria requiring a physical exam (e.g., height, weight, skin condition) will be confirmed after enrollment prior to device placement. 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 before the collection of any study data or performance of any study procedures. A participant who signs an informed consent will be considered enrolled in this study.

A unique identification number will be given to study participants in sequential order. The participant number will consist of 7 digits. The first three digits will designate the site number. The alpha letter represents cohort assignment, and the last three digits will designate the participant by number in sequential order (i.e., participant number 301A101 will be the first participant in cohort A; 301A102 will be the second participant in cohort A, etc.).

7.3 Medical History / Baseline Assessments

Participant demographic information, including age at time of enrollment, race, ethnicity, and sex, will be collected at baseline. In addition, the subject's initials will be collected. Height and weight will be captured to calculate BMI.

7.4 Randomization

Subject will be 1:1 randomized to one of two treatment sequences, stratified by BMI. The study site will receive the randomization envelopes for each cohort that are numbered in sequential order. Within each randomization envelope, a treatment assignment card with randomization ID and treatment sequence assignment will be enclosed. The

randomization envelope should be opened in sequential order only when all eligibility criteria are met.

7.5 Test Procedure

1. After enrollment and randomization, the participant will be brought to the testing area and instructed to undress and put on a gown.
    a. The bed in the test area will be set with clean sheets, a pre-weighed absorbent pad and a pre-weighed urine collection canister.
2. The Health Care Professional (HCP) will complete a visual assessment of the participant's pubic and genital region to ensure that the participant is trimmed and assess the anatomy.
    a. Unless the participant arrives with their pubic hair pre-trimmed, the participant's pubic hair will be clipped by themselves or a trained professional.
    b. The HCP will then complete a brief survey to assess for a buried penis and/or anatomical compatibility with traditional sheath style condom catheters for each participant. "A buried penis refers to a normal-sized phallus encompassed by either skin, subcutaneous tissue, and/or fat in the prepubic area" causing a reduced visible and/or functional length of the phallus.11 for each participant.
3. The HCP will place either the PureWick™ MEC or the Sage PrimoFit™ device (depending on randomized sequence) according to the device IFU and confirm the correct placement.
4. The participant will be placed in a semi-fowler position in the hospital bed and turned to one side using a turning wedge. The HCP should reconfirm correct device placement after repositioning.
5. The HCP will ensure the collection cannister and suction tubing are connected to wall suction and the suction is set to a minimum of 40mmHg continuous suction.
6. Once setup is confirmed and the device is placed, the participant will be allowed to spontaneously void. The participant will be monitored for up to 2 hours, through one void.
7. After the void, the pre-weighed absorbent pad and urine collection canister (with lid) will be weighed and the weights will be documented in the source documents.
8. The Pure Wick MEC or Sage PrimoFit™ will be removed by the HCP according to the IFU and discarded.
9. After removal, the HCP will note any signs of irritation/injury in the perineal area.
    a. Any unresolved erythema (redness), erythema (swelling), bleeding, injury or rash must be recorded as an Adverse Event.

10. The HCP will complete a brief survey to assess device ease of use for the participant just treated.
11. Participant will be asked not to void and to drink approximately 16 ounces of liquid.
12. The second void will be repeated in same manner as the first void using the 2nd device assigned per randomization sequence.
13. When the participant feels the need to void, the HCP will confirm via the bladder scanning that the bladder volume is ≥125mL.
    a. If the volume is determined to be inadequate, the participant will be asked to drink fluids as tolerated and re-assessed in approximately 30 minutes. If the participant does not feel comfortable waiting to void, they will be allowed to proceed with void 2.
14. After device removal, the participant will complete a brief survey to assess device comfort.
15. The HCP will complete a brief survey to assess device ease of use for the participant just treated.
16. Once the second void has completed and all surveys are completed, the participant can be discharged from the study site.

8 PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 Discontinuation/Withdrawal

- A participant may withdraw from the study at any time at his/her own request or may be withdrawn at any time at the discretion of the investigator or sponsor for safety, behavioral, compliance, or administrative reasons. This is expected to be uncommon.
- If the participant withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.
- At the time of discontinuing from the study, no further assessments will be performed.

8.2 Lost to Follow-Up

This study only has one visit thus this is not applicable.

9 ADVERSE EVENTS AND DEVICE DEFICIENCIES

9.1 Definitions of Events

9.1.1 Adverse Events (AEs)

An adverse event 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 (ISO 14155:2020).

Pre-existing conditions should be considered as part of the participant's medical history and should not be reported as an AE unless there is a substantial increase in severity or frequency of the condition, which has not been attributed to natural history. Likewise, planned hospital visits and/or hospital stays should not be considered as adverse events. Exacerbation of an existing condition should be reported as an AE if the event meets the protocol definition of an AE.

The clinical course of the event will be followed according to accepted standards of medical practice until the event resolves, stabilizes, or in the opinion of the Investigator, is no longer considered clinically significant. The Investigator must supply the Sponsor with information concerning the follow up and/or resolution of the AE.

9.1.2 Serious Adverse Events (SAEs)

A serious adverse event is defined by ISO 14155 and/or 21 CFR 803.3 as an adverse event that:

a. led to death;
b. led to serious deterioration in health that resulted in life-threatening illness or injury, resulted in permanent impairment;
c. required inpatient hospitalization/prolonged hospitalization, or resulted in medical/surgical intervention to prevent life-threatening illness/injury or permanent impairment; or
d. led to fetal distress, fetal death, or a congenital abnormality or birth defect.

9.1.3 Adverse Device Effect (ADE) / Serious Adverse Device Effect (SADE)

An adverse device effect is defined as any adverse event that is considered to be related to the use of an investigational medical device. This definition includes any event resulting from insufficiencies or inadequacies in the instructions for

use, deployment, implantation, or operation or any malfunction of the investigational device (study device) and includes any event that is a result of a user error.

A serious adverse device effect (SADE) is defined as an ADE that has resulted in any of the consequences characteristic of an SAE.

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

An unanticipated (serious) adverse device effect (UADE/USADE) is any (serious) adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with, a study device, which by its nature, incidence, severity, or outcome has not been identified in the current instructions for use and/or current version of the risk analysis report, or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of participants.

UADEs/USADEs will be reported to FDA as required by 21 CFR Part 812.

9.2 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

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

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

A. 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.

B. The following categories shall be used for assigning the certainty of the relatedness.

Relatedness	Description
Not Related	Event is independent of study intervention and/or evidence exists that the event is related to another etiology. There must be an alternative etiology documented by the clinician.
Unlikely Related	Event in which the temporal relationship to study intervention makes a causal relationship improbable (e.g., the event did not occur within a reasonable time of the study device use) and in which underlying disease provides plausible explanations (e.g., the participant's clinical condition other concomitant treatments).
Likely Related	Event in which there is evidence to suggest a causal relationship and the influence of other factors is less likely. The event occurs within a reasonable time after use of the study device and is less likely to be attributed to concurrent disease.
Related	Event in which there is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. The event occurs in a plausible time relationship to use of the study device and cannot be explained by concurrent disease.

9.4 Reporting of Events

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

- All SAEs, SADEs, and/or UADEs/USADEs must be reported to the Sponsor within one (1) working day of the site/investigator becoming aware of the event.

- De-identified copies of all requested relevant documentation should be submitted to the Sponsor within 72 hours of knowledge, as appropriate.

It is the responsibility of the Investigator to report adverse events to individual Institutional Review Boards (IRBs)/Ethics Committees (ECs) and/or regulatory authorities according to the local regulations in each participating country.

9.5 Safety Committees

Not applicable

9.6 Device Deficiencies

The Investigator will record a device deficiency if a device used in the study procedure failed to meet its performance specifications whether due to mechanical failure, malfunction, or defect. Device deficiencies also include use errors and inadequate labeling. This applies to: devices used to treat the participant, 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.

All mechanical failures, malfunctions, missing components, and defects of the study devices will be recorded on the appropriate Case Report Form and will be promptly reported to the Sponsor. The device(s) should be returned to the Sponsor as outlined in the site's regulatory binder.

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

Reported deficiencies will be investigated and reported under 21 CFR part 803 Medical Device Reporting by the Sponsor if necessary. The site may be contacted to provide additional information to allow the Sponsor to conduct a thorough investigation.

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.

10 STATISTICAL METHODS

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

10.1 Overview of Study Design

This is a prospective, randomized, crossover, single-blind, single-center healthy volunteer study conducted over 1 day with 2 voids using the PureWick™ Male external catheter vs. the comparator Sage PrimoFit™. This study is designed to assess the performance, comfort, and ease of use of the PW Male external catheter.

A successful hypothesis-test for the primary endpoint (rejection of the Null Hypothesis) will provide evidence to support the superiority of PureWick™ Male external catheter compared with standard of care, in terms of capture rate.

10.2 Sample Size Considerations

Using a two-sided paired t-test at significance level of 0.05, a sample size of 44 provides 90% power to detect a mean paired difference in capture rate that is half of the standard deviation of the paired difference. For example, if the standard deviation of paired difference in capture rate is 10%, a sample size of 44 provide 90% power to detect a mean paired difference of 5%.

10.3 Analysis Population

The following populations are defined:

Population	Description
Enrolled	All participants who sign the ICF.
Intent-to-Treat (ITT)	Enrolled and randomized participants.
Per-Protocol	ITT subjects who are without major protocol deviation.
ITT Subpopulation	ITT subjects who are deemed unable to use traditional sheath style condom catheters.

ITT population will be used for the primary endpoint analysis. ITT subpopulation will be used for the secondary endpoint *with* hypothesis test. Per-protocol analyses may be performed as a sensitivity analysis.

10.4 General Considerations

10.4.1 Handling of Missing Data

Endpoint data may be missing due to reasons including withdrawal of consent, investigator's decision, or loss to follow-up. It is important to minimize missing data and always record the reason for missing. Analyses are primarily based on evaluable data. If there is any indication that missing is related to study endpoints, sensitivity analyses may be carried out to assess the impact of missing data.

10.4.2 Covariates

Confounding introduced by subject characteristics is mitigated by having each subject as their own control. Potential effects of treatment period and sequence will be evaluated using descriptive statistics and regression models.

10.4.3 Multiplicity Control

Study-wise Type I error is controlled using the Fixed Sequence method. The primary endpoint and a secondary endpoint are tested sequentially. The secondary hypothesis will be carried out, only if the primary hypothesis test is successful. Otherwise, the test for the secondary endpoint is considered exploratory.

10.5 Primary Endpoint(s)

Capture rate is defined by:

Captured urine weight / (captured urine weight + leaked urine weight)

The primary endpoint will be evaluated against the following hypotheses:

H_0: Capture rate of PureWick™ Male (system) = Capture rate of established comparator (Stryker/ Sage PrimoFit™)
H_1: Capture rate of PureWick™ Male (system) ≠ Capture rate of established comparator (Stryker/ Sage PrimoFit™)

A two-sided paired t-test will be used to test the hypotheses and p-value will be derived. A p-value < 0.05, combined with a capture rate in favor of PureWick™, indicates that PureWick™ is superior to PrimoFit™ in terms of urine capture.

An exploratory analysis will be performed using regression, where subject may be included as the random effect, and period, sequence, treatment may be included as fixed effects.

10.6 Secondary Endpoint(s)

Secondary Endpoint with Hypothesis Test

If primary endpoint passes the hypothesis test, the same hypothesis test will be performed in the subgroup population of ITT participants who are unable to use traditional sheath style condom catheters. Using the fix-sequence method, the overall type I error is controlled since the test of this secondary endpoint is conditional on the success of the test of the primary endpoint.

Secondary Endpoints without Hypothesis Test

- Overall Comfort score on a 5-point Likert scale (brief questionnaire).
- Ease of use by HCP in placing the MEC (brief questionnaire).

10.7 Other Analyses

No other analyses are needed for this study.

11 DATA COLLECTION AND RECORD MAINTENANCE

11.1 Case Report Forms

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

All required clinical data will be collected/documented in sponsor-provided web-based electronic Case Report Forms (eCRFs). The Investigator may delegate eCRF completion to study personnel. However, the Sponsor must be apprised in writing of the name of such persons and the scope of their authority. The Investigator or designee is obligated to

review each eCRF page and sign EDC, using an electronic signature. An individual record will be kept for each participant that provided informed consent.

Electronic CRFs must be completed as per the BD provided training instructions.

Electronic CRF entries will be compared to source documents by the study monitor or designated personnel. Unless specified otherwise, all information on the eCRFs must be traceable to original source documents. Modification of the eCRFs will only be made if deemed necessary by the Sponsor and/or the appropriate regulatory body.

Site numbers and participant numbers will be used to track participant information throughout the study. Participant personal information will be de-identified. Site numbers and participant numbers will be used to track participant information throughout the study.

11.2 Source Documentation

Original or certified copies of all relevant clinical findings, observations, and other activities throughout the clinical investigation must be recorded and maintained in the study file of each enrolled participant. Where there is no prior written or electronic record of data, such as for subjective data (e.g., pain scales, questionnaires), these data may be recorded directly on the eCRF(s) and thee CRF is then considered to be the source.

11.3 Data Management

Data management is the responsibility of the Sponsor. Data from completed eCRFs will be managed in a secured, controlled database. A Data Management Plan (DMP) will be developed that outlines the procedures used for data review, database cleaning and issuing/resolving data queries. Procedures for validations and data storage will also be contained within the DMP. Observation data will be collected prospectively at the time of each urine output monitoring event. As such, any missing data or inconsistent data cannot be retrieved from an alternate source. Particular care must be taken to ensure that all data are recorded in a clear and complete manner.

11.4 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 product development protocol (21 CFR Part 812.140). 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.

12 QUALITY CONTROL AND ASSURANCE

12.1 Control of Study Products

Investigational study 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 study products, and ensure they are used in accordance with this protocol. Failure to do so may result in the Sponsor suspending or terminating the study at the Investigator's site.

The Investigator will ensure that study products are only dispensed to participants (or used for specimens) properly enrolled in the study. The Investigator must maintain records of receipt, disposition, return and/or destruction of all study products. All investigational study products released to the 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 study product accountability.

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

12.2 Monitoring

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

Prior to study start, a study initiation visit (SIV) will be conducted to review with the Investigator(s) and staff the provisions and proper conduct of this study. This visit will include a detailed review of this protocol, verification that all necessary documents are on file at the investigational site and confirmation of IRB/EC approvals.

During the study, routine monitoring visits (RMVs) will be conducted to assure the site continues to adhere to the protocol, the investigator agreement, and regulations regarding conduct of clinical studies. The Sponsor-Monitor will confirm that the ICF to be used is the version approved by the IRB/EC, confirm the applicable national privacy laws have been followed, verify that all necessary documents are on file at the investigational 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 continued protocol compliance, adequate participant enrollment, accurate data reporting, monitoring of participant safety through identification and/or review of any device-related AEs, UADEs, 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 or 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.

12.3 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 his 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 participant's anonymity must be ensured, and data checked during the audit must remain confidential.

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

12.4 Protocol Deviations

A protocol deviation is defined as an event where the Investigator or site personnel did not conduct the study according to the protocol.

Except when necessary to protect the life or physical well-being of a participant, protocol deviations are not permitted. The Sponsor and the investigational site's IRB/EC must be notified immediately if an emergency situation arises in which the safety of a participant may require immediate intervention different than that defined in the protocol. 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 Investigator's responsibility to ensure that there are no deviations from the Protocol. Except in an emergency, when a protocol deviation is planned or anticipated, the Sponsor should be contacted for approval. Any and all deviations must be recorded on the appropriate CRF regardless of whether medically justifiable or sponsor approved. Upon evaluation by the Sponsor, actions may be required to prevent additional deviations, such as retraining of the site, implementation of additional site procedures, and more frequent monitoring. If these steps fail, more serious measures, up to and including termination of enrollment at the site.

13 ADMINISTRATIVE REQUIREMENTS

13.1 Investigator and Site Selection

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

The Principal Investigator will sign the Investigator Agreement pages of this protocol, agreeing to comply with all applicable regulations and the requirements of this study

13.2 Training

In addition to each Investigator and appropriate site personnel being trained on this protocol and study procedures during the Site Initiation Visit, product training will be provided by the Sponsor or designee and is required for each Investigator. Additional study staff (e.g., 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 investigational site and with the Sponsor.

13.3 Required Documents

An Investigator may not screen or enroll participants 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 Non-disclosure Agreement (NDA) between PI/site and Sponsor;
- CVs, signed and dated within 2 years of study start for the PI and Sub-Investigator(s);
- CVs for Study Coordinator(s);
- Signed CSA by PI/site (or designee);
- Signed Investigator Agreement Page by PI and Sub-Investigator(s);
- Signed Financial Disclosure Statement by PI and Sub-Investigator(s);
- Completed and Signed Training Log by PI and Sub-Investigator(s);
- Study Personnel Identification list;
- Written approval from the IRB/EC of both the protocol and ICF, and any other applicable protocol specific material; and
- IRB/EC Membership List, Assurance of Compliance Form, or equivalent.

13.4 Publication Policy

The sponsor believes that results of applicable clinical studies should be published in peer-reviewed literature in a timely, accurate, complete and balanced manner, regardless of study outcomes, whenever possible. As such, at the conclusion of this study, an article may be prepared for publication in a reputable scientific journal. Formal presentation(s) or publication(s) of data collected from this study will be considered as a joint publication

by the investigator(s) and the appropriate personnel of the Sponsor. Authorship will be based on generally accepted criteria of the ICMJE (International Committee of Medical Journal Editors) and determined by mutual agreement.

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

13.5 Study Registration

In compliance with Title VIII of Public Law 110-85, known as FDA Amendments Act of 2007 (FDAAA), the Sponsor will register this study studies and disclose study results in a publicly accessible database (i.e., ClinicalTrials.gov). This study will be registered no later than 21 days after commencing enrollment. Study results will be posted to the website within 12 months of the last participant visit.

13.6 Termination of 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 investigational site for reasons including, but not limited to, inadequate data collection, low participant enrollment rate, achievement of the total enrollment, conditions imposed by the reviewing IRB/EC and/or non-compliance with this protocol or other clinical research requirements. 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.

14 ETHICAL AND REGULATORY CONSIDERATIONS

14.1 IRB/EC Approval

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

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

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

14.2 Informed Consent and Confidentiality

Prior to any study procedure, the Investigator (or designee) must explain to each participant in layman's terms, the nature of the study, its purpose, expected duration, and the risks and benefits of study participation. Also, participant 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 (e.g., HIPAA requirements in the U.S.) will be followed in this study. The participants 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. Participants 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 participant must voluntarily provide consent in accordance with 21 CFR Parts 50 and 56 and ISO 14155:2020(E). The participant will receive a copy of his/her signed ICF.

14.2.1 Confidentiality

Participant confidentiality must be strictly held in trust by the Investigator, study staff, and the Sponsor. Participant confidentiality and anonymity will be

maintained by removal of identifiers from any data, documentation, or clinical samples submitted to the Sponsor.

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

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

14.3 Regulatory Status

The PureWick™ Male External Catheter is a Class I, 510(k) exempt device currently marketed in the United States and will be evaluated for its approved indication. The comparator device, Sage PrimoFit™, is also a commercially available device which is Class I, 510(K) exempt. Institutional Review Board (IRB) submission of this study plan along with IRB study approval or waiver is required.

14.4 Statement of Compliance

This clinical investigation will be conducted in compliance with the protocol and following regulatory requirements:

- 21 CFR 50, 54, 56 and 812;
- 21 CFR 812.28(a)(1) (Good Clinical Practice);
- ISO14155:2020 (Good Clinical Practice);
- Ethical principles of the Declaration of Helsinki, in its current revision; and
- Applicable sections of the national laws and regulations.

The clinical investigation will not commence at a clinical site until approval (favorable opinion) from the respective IRB/EC has been received. All additional requirements imposed by the IRB/EC(s) will be followed. Involvement of the national competent authorities (e.g., by notification, seeking authorization) will be accomplished as required by national laws and regulations.

15 REFERENCES

1. Beeckman D, Van Damme N, Schoonhoven L, Van Lancker A, Kottner J et al. (2016) Interventions for preventing and treating incontinence-associated dermatitis in adults. Cochrane Database Syst Rev 11 CD011627.
2. Bender JK, Faergemann J, Skold M (2017) Skin Health Connected to the Use of Absorbent Hygiene Products: A Review. Dermatol Ther (Heidelb)
3. Beeckman D, Van Lancker A, Van Hecke A, Verhaeghe S (2014) A systematic review and meta-analysis of incontinence-associated dermatitis, incontinence, and moisture as risk factors for pressure ulcer development. Res Nurs Health 37 (3): 204-218.
4. Beeckman D, et al. (2015) Proceedings of the Global IAD Expert Panel. Incontinenceassociated dermatitis: moving prevention forward. Wounds International Available to download from www.woundsinternational.com.
5. Chant C, Smith OM, Marshall JC, Friedrich JO (2011) Relationship of catheter-associated urinary tract infection to mortality and length of stay in critically ill patients: a systematic review and meta-analysis of observational studies. Crit Care Med 39 (5): 1167-1173.
6. Tandogdu Z, Bartoletti R, Cai T, Cek M, Grabe M et al. (2016) Antimicrobial resistance in urosepsis: outcomes from the multinational, multicenter global prevalence of infections in urology (GPIU) study 2003-2013. World J Urol 34 (8): 1193-1200.
7. CATHETER, U. C. M. E. (2008) Good Practice in Healthcare: Male External Catheters, Condom Catheter Urinary Sheath. EAUN MEC Guidelines
8. Staniorski, C. J., & Rusilko, P. J. (2021). The concealed morbidity of buried penis: a narrative review of our progress in understanding adult-acquired buried penis as a surgical condition. Translational Andrology and Urology, 10(6), 2536.
9. Mirastschijski, U. (2018). Classification and treatment of the adult buried penis. *Annals of Plastic Surgery*, *80*(6), 653-659.
10. Fuller, T. W., Theisen, K. M., Shah, A., & Rusilko, P. J. (2018). Surgical management of adult acquired buried penis. Current Urology Reports, 19, 1-8.
11. 11. Ho, T. S., & Gelman, J. (2018). Evaluation and management of adult acquired buried penis. *Translational Andrology and Urology*, *7*(4), 618.

16 APPENDICES

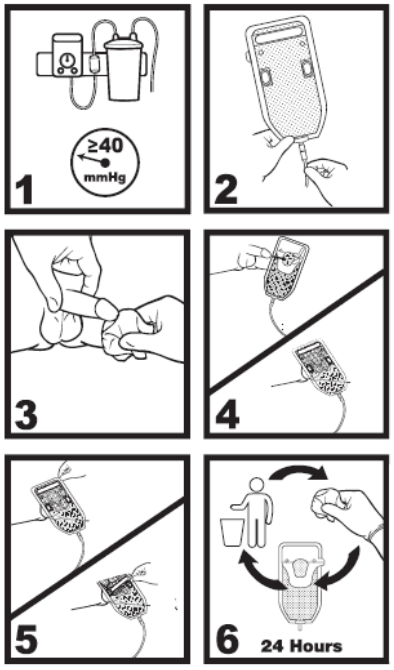
16.1 Appendix 1: PureWick™ Male External Catheter Instructions for Use (IFU)

Instructions for Use

PUREWICK™
MALE EXTERNAL CATHETER

Male External Catheter Kit
Contents:

1 PureWick™ Male External Catheter
1 Pack Peri-Care Wipes
1 Drying Wipe

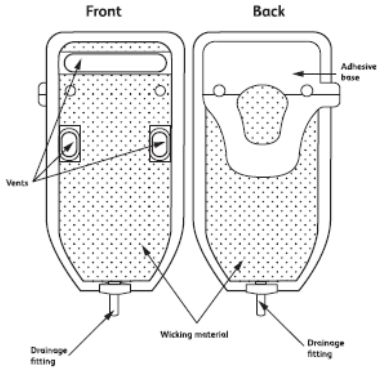


Setup:

1. Connect a canister to wall suction and set to a minimum of 40mmHg continuous suction. Always use the minimum amount of suction necessary.
2. Using standard suction tubing, connect the device to a collection canister.
   Note: Collection canister and suction tubing are not included. If hospital policy allows and if using a graduated canister, captured urine may be used for approximate urine output measurement.

Peri-care and Placement:

3. If there is significant pubic hair, trim or clip the pubic hair. Perform perineal care using the included wipes and assess skin integrity. Follow and document per hospital protocol.
   Note: Use the included drying wipe to ensure skin is dry prior to placement of the device. Moisture on skin will weaken the adhesive.
4. Orient the device, aligning drainage fitting towards the feet of the patient. Slide the opening of the device over the penis until close to the pelvic skin. Center penis within the opening. Remove adhesive liner and press the device against the pelvic skin to adhere. Ensure base has fully adhered around the base of the penis.
   Note: The scrotum should not be placed inside the device.



Removal:

5. To remove the device, gently lift the top edge of the device off the skin. In a slow, downward peeling motion, remove the device. If necessary, use a warm wet compress (such as a wet washcloth) to help loosen adhesive.
   Warning: To avoid potential skin injury, never pull the device directly away from the patient. Always peel in the direction from head to foot.

Maintenance:

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

BARD

Protocol Number: UCC-23AC022 CONFIDENTIAL

Version:1.0

Date: 16May2023

PUREWICK™
MALE EXTERNAL CATHETER

Indication for use:
The device is intended for non-invasive urine output management in male patients.

Contraindications:
- Patients with urinary retention

Warnings:
- Do not use on irritated or compromised skin.
- Do not cover fresh surgical wounds with the device.
- Do not use the device with any material or in any position that does not allow for sufficient airflow.
- To avoid potential skin injury, never pull the device directly away from the patient. Always peel in the direction from head to foot.
- Discontinue 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 patients who are:
  - Agitated, combative, or uncooperative and might remove the device.
  - Having frequent episodes of bowel incontinence without a fecal management system in place.
  - Experiencing skin irritation or breakdown at the site.
- Do not use barrier cream on the penis or pubic skin around the base of the penis when using the device. Creams may impede suction or weaken adhesive.
- Proceed with caution in patients who have undergone recent surgery of the external urogenital tract, penis, or pubic area.
- Always assess skin for compromise and perform perineal care prior to placement of a new device.

Recommendations:
- Perform each step with clean technique.
- Prior to connecting the device to hospital wall suction tubing, verify suction function by covering the open end of the suction tubing with one hand and observing the pressure dial. If the pressure does not increase when the line is covered, verify that the tubing is secured, connected, and not kinked.
- Ensure the device remains connected after turning the patient, monitoring for pulling and tension on the device. Remove the device prior to ambulation.
- Assess device placement and patient's skin at least every 2 hours.
- Change suction tubing per hospital protocol or at least every thirty (30) days.

Units	EXTERNAL USE ONLY
Single Use	Non-sterile
REF Catalog Number	Do not use if package is damaged
LOT Lot Number	Use By date

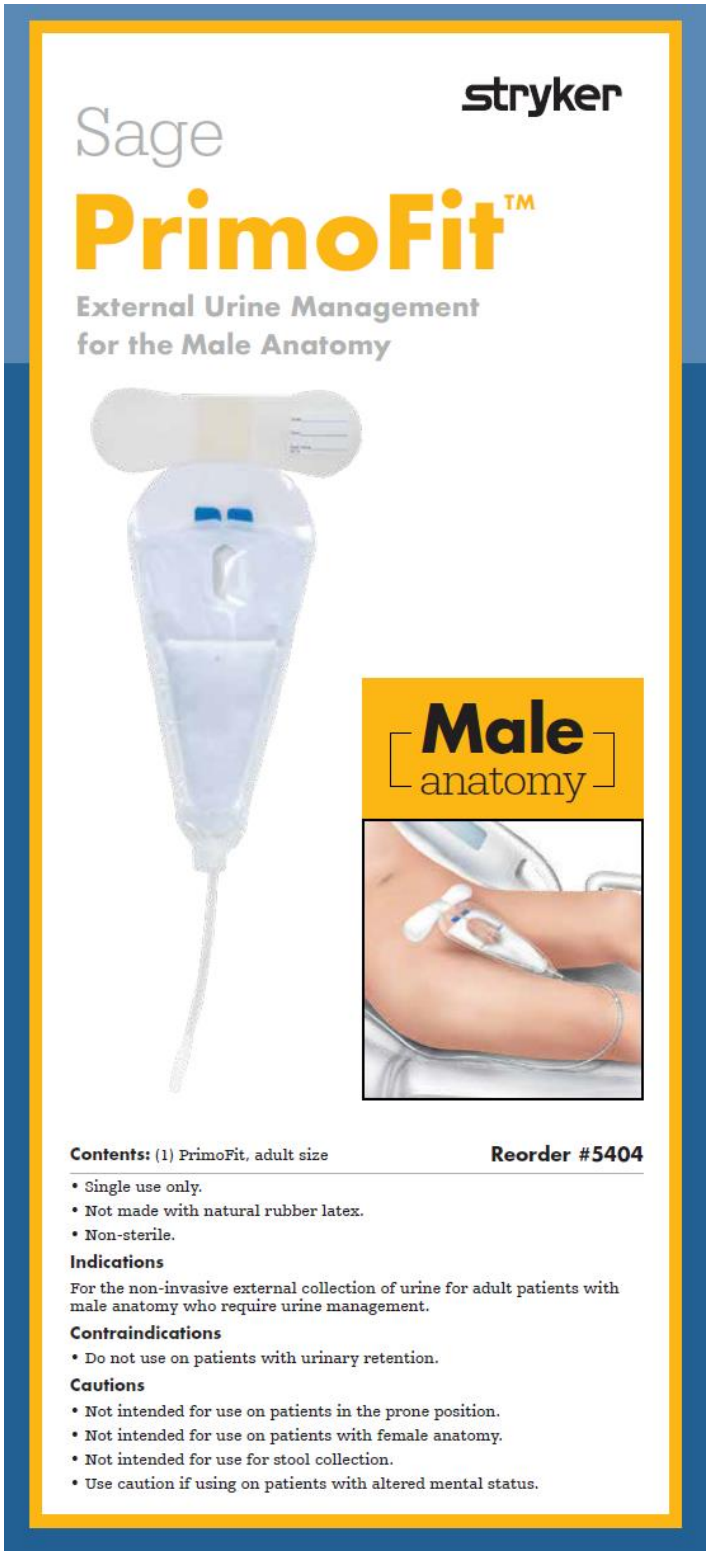
Not Made with Natural Rubber Latex

BARD

Manufacturer:
C. R. Bard, Inc.
8195 Industrial Blvd
Covington, GA 30014 USA
1-844-823-5433
www.purewick.com
bd.com

PK0330325 07/2021

16.2 Appendix 2: Sage PrimoFit™ Instructions for Use (IFU)



Protocol Number: UCC-23AC022 CONFIDENTIAL

Version:1.0

Date: 16May2023

Supplies needed

- Suction canister
- Suction tubing

Directions

Prior to use

- Perform skin assessment every 2 hours per hospital protocol.
- Refer to manufacturer's instructions for suction set up.
- Ensure patient meets hospital protocol prior to placing device. If necessary, clip patient hair per hospital protocol.

Placement

Step 1 Set up suction canister and tubing according to hospital protocol. Replace tubing and empty and/or replace suction canister per hospital protocol.

Step 2 Place patient in supine position and separate patient's legs.

Step 3 Clean, prep and dry patient's genital area according to hospital protocol. If necessary, clip patient hair per hospital protocol.

Step 4 Remove device from packaging.

Step 5 Remove the base adhesive liner. **(Figure 1)**

Step 6 Position the device with adhesive side toward the patient, with the tabs facing upward and the opening of the base adhesive in line with the patient's penis.

Step 7 Holding the tabs, position the base adhesive up and around the patient's penis against the skin. To ensure adequate adhesion, apply pressure all the way around the base adhesive against the skin. **(Figure 2)**

Step 8 Position the patient's penis into the chamber. **(Figure 3)**

Step 9 Remove the adhesive pad liner **(Figure 4)**. Pull the device up until fully extended over the patient's penis and suprapubic region and adhere the adhesive pad onto the patient's abdomen. **(Figure 5)**

Step 10 Ensure adequate length of suction tubing is available. Attach suction tubing to the device at the suction tubing adapter. Ensure connection of suction tubing to device is secure and connected at all times while device is in use. Confirm there are no kinks in the tubing and that tubing does not run under the patient. **(Figure 6)**

- Secure tubing per hospital protocol.

Step 11 Set vacuum to low, continuous suction at a minimum of 60mmHG. Always use the minimum amount of suction necessary.

Step 12 Return patient's legs to a closed position.

- Assess device periodically to ensure proper placement, particularly after turning or repositioning patient.
- Device can be left in place for up to 24 hours. Replace device if soiled with stool or bodily fluids other than urine. Discard device according to hospital protocol and local regulations.

Removal

Step 1 Place the patient in the supine position and separate patient's legs.

Step 2 Gently remove the adhesive pad from the patient's abdomen.

Step 3 Remove the patient's penis from the chamber.

Step 4 Gently remove the base adhesive by pulling the tabs down and away from the patient's penis.

Step 5 Assess skin integrity and perform perineal care.

Step 6 Disconnect device from suction tubing and discard device according to hospital protocol and local regulations.

Discontinue use

- When independent or assisted toileting is feasible.
- During patient ambulation.

For a French-Canadian translated version of the instructions for use contact Stryker Customer Service at 800 323 2220. In Canada, this product is not intended to be sold to the general public.

R48050

Product part identification:

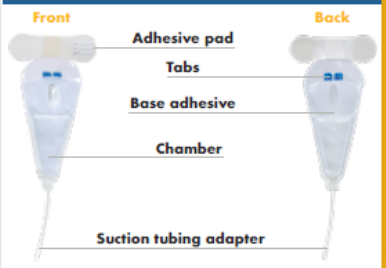


Figure 1

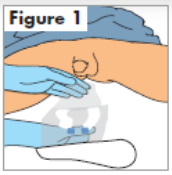


Figure 2

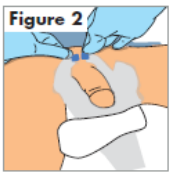


Figure 3

Figure 4

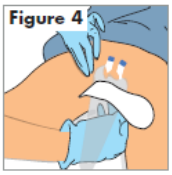


Figure 5

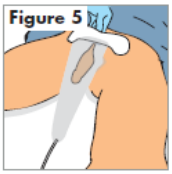
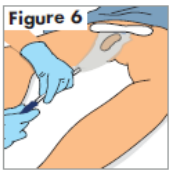


Figure 6



Manufactured for: Sage Products LLC
3909 Three Oaks Road • Cary, IL 60013
800 323 2220 • stryker.com
Assembled in U.S.A.
U.S. Patents: stryker.com/patents

6 18029 60044 8

16.3 Appendix 3: Participant Comfort Scale Survey

To be completed by each participant once per device (total of 2 per participant).

Participant Number:	Void # (Void 1 or Void 2)

Now that you have experienced the use of the device as well as voiding with the device in place, please answer the following questions considering the use of the current male external catheter.

1. On a scale of 1 to 5 where 1 is very uncomfortable and 5 is very comfortable, how comfortable was the placement of the male external catheter?

1	2	3	4	5
Very uncomfortable	Uncomfortable	Neither comfortable nor uncomfortable	Comfortable	Very Comfortable

2. On a scale of 1 to 5 where 1 is very uncomfortable and 5 is very comfortable, how comfortable was the device while you were voiding?

1	2	3	4	5
Very uncomfortable	Uncomfortable	Neither comfortable nor uncomfortable	Comfortable	Very Comfortable

3. On a scale of 1 to 5 where 1 is very uncomfortable and 5 is very comfortable, how comfortable was the removal of the male external catheter?

1	2	3	4	5
Very uncomfortable	Uncomfortable	Neither comfortable nor uncomfortable	Comfortable	Very Comfortable

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 male external catheter to one of your loved ones?

1	2	3	4	5
Very Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Very Likely

16.4 Appendix 4: Professional Ease of Use Questionnaire

To be completed by HCP after each participant void.

HCP:		Void #:		
Now that you have experienced the application and removal of the device for this participant, please answer the following questions using your professional opinion in regard to device ease of use for this specific participant.				
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?				
1 Very difficult	2 Somewhat difficult	3 Average difficulty	4 Somewhat easy	5 Very easy
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?				
1 Very difficult	2 Somewhat difficult	3 Average difficulty	4 Somewhat easy	5 Very easy