INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Medline Industries, LP / "Evaluation of a Wetness Sensing System for Continence Care"**
Protocol Number:	**MED-2021-DIV82-002**
Principal Investigator:	**Tia L. Albro, ACNP-RN**
Telephone:	**585-288-0890 (24-Hours)**
Address:	**Rochester Clinical Research, Inc.** **500 Helendale Road** **L20 & Suite 200** **Rochester, NY 14609**

PURPOSE

The purpose of this research study is to validate the FitRight® System sensor's ability to detect when an adult brief has absorbed enough liquid via simulated urinary void (to eliminate waste from the body) to trigger an alert to change the study brief in the sitting, supine (laying on your back), and right or left side positions.

This is a research study to test a new investigational device. An investigational device is one that is not approved by the United States Food and Drug Administration (FDA).

INTRODUCTION TO RESEARCH

This is a clinical research study for Medline Industries, LP, a medical device company. Clinical research is the study of human conditions in an attempt to improve treatment or gain knowledge. In order to decide whether you agree to be a part of this study, you should understand enough about the risks and benefits to make an informed decision. Your participation in this study is voluntary. Please read this consent carefully and discuss it with the study staff. If you have any questions about or do not understand something in this form or about the study, you should ask the investigator or study staff. You should not sign and date this form if you have any questions that have not been answered.

The investigator is being paid by Medline Industries, LP to conduct this research.

NUMBER OF PARTICIPANTS EXPECTED

There are 56 participants expected to be in the study.

DURATION OF STUDY

Your participation in this study will last approximately two hours and will include one study visit.

PROCEDURES

Informed Consent and Screening

The study will take place at Rochester Clinical Research in a clinical exam room or an equivalent, private area. Study staff will go through the informed consent document with you. If you agree to be in the study, you and study staff will sign and date the informed consent document.

After signing and dating this consent, you will be asked a series of screening questions about your age, gender, and brief medical history. If you qualify and voluntarily agree to participate in the study, you will be enrolled and randomized, like the flip of a coin, to determine the side position you will be placed in (left or right side).

Application of the Study Product

You will be sized by study staff with the brief sizing tools and given the study brief for your size. You will be given space to privately apply the study brief (according to the instructions for use (IFU)) and tubing. Once the study brief is on and tubing is in place, study staff will apply exam gloves and assess the study brief for correct application. If the study brief or tubing needs to be adjusted, you will be given more time to privately make adjustments. The tubing should be placed directly in the center of the bottom of the study brief at the approximate location of urination.

Once the tubing is in place and the study brief is applied correctly, you will be instructed to sit on the bed in a sitting position. If the tubing moves, you should again adjust the tubing to the correct position. Study staff will then apply the study pod to the study brief (according to the IFU) and make sure the app is working. Study staff will then connect the tubing in the study brief to the tubing connected to the funnel system.

Normal Saline Pours

Once the study system is properly setup, the study staff will pour 90 milliliters (mL) of normal saline (first pour) through the funnel system to enter the study brief. Study staff will immediately start a calibrated timer for five minutes once the saline drains from the funnel system. After the five minutes, study staff will document whether the study brief did or did not trigger an alert. If the study brief triggers an alert you are ready for the next study brief. If the study brief does not trigger an alert, study staff will pour an additional 150mL normal saline (second pour) through the funnel system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system.

After the five minutes, study staff will document whether the study brief did or did not trigger an alert. If the study brief triggers an alert you are ready for the next brief. If the study brief does not trigger an alert, study staff will pour an additional 120mL normal saline (third pour) through the funnel system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system.

After the five minutes, study staff will document whether the study brief did or did not trigger an alert. If the study brief triggers an alert you are ready for the next brief. If the study brief does not trigger an alert, study staff will pour an additional 120mL normal saline (fourth pour) through the funnel system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system. After the five minutes, study staff will document whether the study brief did or did not trigger an alert. No matter if the study brief did or did not trigger an alert you will move onto the next brief.

You will be asked to remove the study brief and apply a new brief (in your appropriate size) with new tubing. You will be asked to lay in a supine (laying on your back) position and study staff will perform the same steps as above. Once the study staff completes all steps, you will be asked to remove the study brief and apply another new brief (in your appropriate size) with new tubing. You will be asked to lay on either your right or left side (the side you are randomized to) and study staff will perform the same steps as above. Once the study staff completes all steps, you will be asked to remove the study brief.

Rewet Procedures

You may be asked to perform the Rewet Procedures as a part of your participation in this study. You will apply another study brief (in your appropriate size) and new tubing. Study staff will confirm correct application of the study brief. The study pod and app will not be used for this testing. You will be asked to sit on the bed in the sitting position. Study staff will pour 360mL normal saline through the funnel system to enter the study brief. Study staff will immediately start a calibrated timer for ten minutes once the saline drains from the funnel system. After the ten minutes, you will be asked to remove the study brief and give the brief to the study staff. Study staff will then perform rewet testing procedures with the study brief.

POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY

This study entails minimal risk. The FitRight® System will be applied and operated according to the IFU. There is the possibility of minor skin irritation from the study brief due to saline interaction, however, none is anticipated. In addition, the study products will also be applied on non-compromised skin with no known skin conditions, which should impose less risk.

If you do not understand what any of these side effects or risks mean, please ask the investigator or study staff to explain these terms to you. You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study. You might have other side effects or discomforts that are not listed in this form.

There may be risks that are unknown.

POTENTIAL BENEFITS OF THE STUDY

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

This research study is not intended to diagnose, treat, or prevent any disease and is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study.

CONFIDENTIALITY AND DISCLOSURE AGREEMENT STATEMENT

Your identity will be kept confidential as per the Health Insurance Portability and Accountability Act (HIPAA), except where disclosure is required by law. As part of this research, the investigator will collect health data and procedures. Health data may include: your age, gender, and a brief medical history.

Your information may be used and shared with these people for the following purposes:

- The investigator and study staff to conduct this research.
- The sponsor, people who work with or for the sponsor and other researchers involved in this study. These people will use your information to review the study, and to check the safety and results of the study.
- Others required by law to review the quality and safety of research, including the United States (U.S.) Food and Drug Administration (FDA), Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries to be sure applicable laws are being followed; and the Institutional Review Board (IRB) to protect the rights and safety of participants.

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information. Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here. We cannot promise complete confidentiality. To maintain the integrity (quality) of this research, you might not have access to health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

If the results of this study are published, your name or other personal information will not be included. You can cancel your authorization to use and share your information at any time by writing a letter to the investigator at the address listed on the first page of this form. If you cancel your authorization, you will not be able to continue in the study and the investigator and study staff will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years or as applicable by local law.

Information from this study will be submitted to the sponsor, and possibly to the Food and Drug Administration (FDA) and to governmental agencies in other countries where the study device may be considered for approval. Information sent from the study site may contain a participant number, but will not contain your name.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You will not be provided the results of the study.

COMPENSATION FOR PARTICIPATION

The data and/or results collected from your participation in this study may lead to profitable gains for Medline Industries, LP in the future. You will not share in any profits.

If you agree to participate in the study, you may be paid up to a total of $150.00. You will be paid following the conclusion of your study visit. If you choose to leave or are withdrawn from the study for any reason, you will not be paid. You will also receive a towel to use during your study visit and you will take it home at the end of your visit.

COMPENSATION FOR INJURY

If you become ill or are hurt while you are in the study, call the investigator immediately. If you are injured or become sick during the study, you should seek medical treatment as needed and tell the investigators as soon as possible. If you suffer an adverse reaction, illness, or injury which was directly caused by the investigational device or any properly performed procedures required by the study, the sponsor shall pay for reasonable medical expenses necessary for immediate treatment of your injury to the extent that your expenses are not covered by your medical insurance or any other third-party coverage and provided that you have followed the directions of the investigator. Provision of such medical care is not an admission of legal responsibility. The sponsor has no plans to provide any other form of compensation, such as for lost wages, disability or discomfort.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS

There is no charge for your participation in this study. The study device will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00063388.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to participate in this study is voluntary. Refusal to participate or leaving the study at any time will involve no penalty or loss of benefits to which you are otherwise entitled to at this site. You are free to withdraw from the study at any time. Please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Your participation in this study may be stopped at any time by the investigator or the Sponsor without your consent for any reason, including: if it appears to be medically harmful to you, if you fail to keep your scheduled appointments, if the study is canceled, if you do not consent to any future changes that may be made in the study plan, or for administrative reasons.

You do not give up any legal rights by signing and dating this consent form.

CONSENT AND AUTHORIZATION

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this consent document.

_____
Print Name of Participant

_____ _____
Participant Signature Date

_____
Printed Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date