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 / "An evaluation of the skin protection characteristics of two commercially available skin barrier protectants"**
Protocol Number:	**MED-2022-DIV71-003**
Principal Investigator: (Study Investigator)	**Julie Miller, RN, BSN, CCRA**
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Address:	**Medline Industries, LP** **Three Lakes Drive** **Northfield, IL 60093** **Medline Industries, LP** **1 Medline Pl** **Mundelein, IL 60060**

If you are an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

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 study investigator or study staff. You should not sign this form if you have any questions that have not been answered.

PURPOSE

The purpose of this research study is to evaluate and compare the duration of wear and durability of the Marathon® and Cavilon™ skin barrier protectants (SBPs).

These study devices are already on the market meaning these products have been cleared for marketing by the United States Food and Drug Administration (FDA).

The use of these products in this research study is investigational.

NUMBER OF PARTICIPANTS EXPECTED

There are 42 participants expected to be in the study.

DURATION OF STUDY

Your participation in this study will last up to 13 days.

PROCEDURES

Pre-Visit Activities –Informed Consent, Screening, and Washout

The pre-visit activities will take place at Medline Industries, LP in a private room or via video conference call. We will go over this informed consent document and if you agree to be in the study, you and study staff will sign and date this informed consent form. After signing and dating this consent, you will complete the screening process by verbally answering questions regarding your age, gender, and brief medical history. If you qualify for the study, you will be instructed to avoid applying any perfumes, moisturizing, skin hydrating, or body cleansing products on both forearms/inner elbows for a minimum of 18 hours prior to Visit 1. This is called a washout period.

Visit 1 – Baseline Measurements, Study Product Application, Post Application Measurement

Visits 1-6 will take place onsite at your indicated Medline facility. If you have any COVID-19 symptoms you are instructed not to enter Medline campus. For the duration of Visits 1-6 you will be asked to wear clothing that will allow both forearms and inner elbows to remain exposed. Visit 1 will take approximately 30 minutes. Upon confirmation of successful completion of the washout period, you will wash both forearms and inner elbows with a standardized soap, dry each arm with paper towels, and allow them to fully dry. Study staff will use a non-toxic marker and calibrated ruler to draw six 2 inch x 2 inch squares on your forearms and inner elbows. Using a Corneometer (a non-invasive device that measures moisture content of skin), study staff will take initial measurements to measure baseline skin hydration of each of the six forearm and inner elbow locations.

You will be randomly assigned (like a coin toss) to study product location sites on your forearms and inner elbows where each skin barrier protectant will be applied. This is a single-blinded study, thus you will not know the assignment of each study product to the corresponding arm location. Study staff will then apply each study product within the border of the randomly assigned test site squares. Once the study products fully dry (at least one minute), Corneometer measurements will be taken from each of the six study treatment and control squares. After the measurements are taken, you will be asked to complete a short survey about the study products. Following these activities, you will be permitted to leave and instructed to return to the room the following day and remaining days after to complete Visits 2-6. You will also be provided a standardized soap to take home to use for bathing your arms at home for the duration of your study participation. You are asked to minimize any scrubbing or any other abrasion of the skin of the inner forearms and elbows.

Visits 2-6 –Post-application Measurements

Visits 2-6 will take approximately 15 minutes to complete. Upon returning to the evaluation room each day, study staff will take another set of Corneometer measurements from each of the six test areas. After the measurements are taken on Visits 3 and 6, you will be asked to complete a short survey about the study products. Following these activities, you will be permitted to leave and instructed to return to the

room the following day and remaining days until you finish Visit 6, after which you will be dismissed from the study.

Visits 1-6 will only be performed on Monday-Friday. Visit 1 will always take place on either Monday or Tuesday. See example schedules below:

	Study start day	
Activity	Monday	Tuesday
Remote Consent/Screening visit	Thursday/Friday	Thursday/Friday
Start washout period	Sunday	Monday
Visit 1	Monday	Tuesday
Visit 2	Tuesday	Wednesday
Visit 3	Wednesday	Thursday
Visit 4	Thursday	Friday*
Visit 5	Friday*	Monday
Visit 6	Monday	Tuesday
*No visit activity on Saturday or Sunday		

Study staff will remind you throughout your participation that you should only be bathing your arms with the standardized soap provided by study staff for the duration of your study participation. You will also be reminded to minimize any scrubbing or any other abrasion of the skin of the inner forearms and elbows.

POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY

This study entails minimal risk to study participants. The SBPs used in the study are commercially available products that can be used in both home and clinical settings. There is a possibility of minor skin irritation and redness, however, the magnitude of this should be no greater than what occurs through normal use of the currently marketed SBPs. The SBPs will also be applied on unbroken, non-compromised skin which should minimize risk.

If you do not understand what any of these side effects or risks mean, please ask the study investigator or study staff to explain these terms to you. You must tell the study 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.

If you become pregnant during your participation in this study, notify the study Investigator or study staff immediately.

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 study investigator will collect health data and the results of your study-related surveys 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 study 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 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. We cannot promise complete confidentiality. To maintain the integrity 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 study investigator at the address listed on the first page of this consent form. If you cancel your authorization, you will not be able to continue in the study and the study 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.

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 $250. You will be paid for the visits you complete ($38/Visit 1-5; $60/Visit 6). Payments will be made via direct deposit and may take up to 4 weeks after the completion of your participation.

If you choose to leave or are withdrawn from the study for any reason, you will be paid for each completed visit.

COMPENSATION FOR INJURY

If you become ill or are hurt while you are in the study, call your study investigator immediately. If you are injured or become sick during the study, you should seek medical treatment as needed and tell the study investigator as soon as possible. If you suffer an adverse reaction, illness, or injury which was directly caused by the investigational devices 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 study 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 devices will be provided at no charge to you or your insurance company. Routine medical care outside the scope of this study may still be your responsibility.

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 study Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study 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 any 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: Pro00065625.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to participate in this study is voluntary. Refusal to participate 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 study Investigator, Sponsor, or IRB 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 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 and to allow study staff to collect, use, and share my health data as specified in this form until I decide otherwise. I do not give up any of my legal rights by signing 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