IRB OUTLINE FOR THE DISPOSABLE LEG WRAP STUDY

STUDY TITLE: Pilot Evaluation of a Disposable Multi-layered Absorbent Lower Extremity Wrap for Management of Exudative Lower Extremity Edema.

STUDY PURPOSE: To evaluate the feasibility, safety, and user acceptability of a patented single-use three-layer disposable leg wrap designed to absorb and contain lower-extremity fluid drainage associated with exudative lower extremity edema (AKA: "weeping edema).

STUDY OVERVIEW:

Device Name: Disposable Leg Wrap

Intended Use: Patented disposable Class 1 wound dressing for the management of external lower leg exudate (AKA: Weeping Edema).

Study Duration: 3 to 6 days contingent on dressing change frequency (every 12 hours for heavy drainage VS 24 hours for light drainage).

Participants:

1. Assenting adults with a current episode of lower-extremity weeping edema who have received at least 3 days of traditional treatment or have a history of traditional treatment for previous episodes.

2. A non-professional caregiver who will provide dressing changes in the home setting after being provided with standardized teaching provided by a research-appointed RN. This person may also be the subject's legal medical representative.

3. Current RN case manager who will help provide oversight, in tandem with the research team.

DETAILED STUDY PROCEDURES:

A. Patient population: Subjects for this study will be current Patients living in a home environment, receiving services within the [redacted] Medical Center Home Health, or Hospice departments.

B. Finding study subjects: Communication will be provided to the appropriate individuals employed within the Hospice system about this pilot study. They will identify potential subjects who may likely meet the criteria for this study.

C. RN Case manager initial role: After obtaining clearance from their manager (other pre-determined in-house authority), the assigned RN case manager for these home patients will make an initial determination regarding patients' ability to assent to participate in this study, and if there is interest in receiving more information about what will be required on their end. (see details regarding assent/consent in section ____ of this brief).

D. Can we proceed? If the subject meets the inclusion criteria without exclusionary issues and is interested in participation, an email is sent to the Leg Wrap research P.I., who will contact the designated research study RN. In there is no interest, no other actions are taken.

D. Designated RN initial contact: The designated research study RN will make initial contact by phone with the subject or their medical legal representative to provide standardized basic information about this study and determine if they meet inclusion criteria and if there is interest in participating in the study.

E. P.I. final screening for participation: If there is interest and it appears the necessary criteria are met, the designated research study RN will contact the research P.I. to review information collected on each potential participant. This information will be used to determine next steps.

F. Assigned subject ID number: Each participant is assigned a 4-digit ID number to protect the patient's PMI for this study. This number will be provided to the designated research RN.

G. Visit arranged: The designated RN will contact the Patient or representative to schedule a visit appointment.

During this contact, information will be gathered on what supplies are already present in the home to avoid bringing unnecessary supplies into the home. (e.g., skin cleanser, cream, chux, gauze pads).

H. Designated research RN visit:

This visit is to provide standardized teaching to the designated caregiver, who must agree to provide all dressing changes during this study to ensure consistency and safety. At visit:

1. RN introduction. Sort the supply and provide what is needed.

2. Review of 5 min step by step Leg Wrap teaching video. Show how to access this video via the link(s) provided on the outside of each Leg Wrap pouch so the caregiver can review as needed.

3. RN provides a hands-on demonstration of dressing application.

4. Designated caregiver provides a "teach back" demonstration to ensure understanding of how to provide this care.

5. RN checks to ensure all questions have been addressed and that the caregiver feels confident in performing the necessary dressing changes using the Leg Wrap before ending the visit. RN explains that she will follow up in 24 hours for an initial check-in and will also check in approximately 1 week after the expected completion of the study to ensure the survey has been completed.

J. Contact number:

This contact number is yet to be determined but will be available to all participants as a resource for questions or concerns directly related to the study.

RESEARCH STUDY VS. STANDARD CARE/WEEPING LEG EDEMA:

Standard Care: Standard care for weeping leg edema typically includes the following:

Standard clinical care for participants with weeping lower-extremity edema consists of clinician-directed evaluation and management of the underlying edema, routine skin assessment, primary wound dressing as indicated, and the use of absorbent dressings and/or compression-based interventions when clinically appropriate. Standard care often involves cumbersome dressing changes with materials such as Kerlix, ABD pads, and Coban.

Participants in this pilot study will continue their prescribed treatment plan under the care of their treating provider. The investigational disposable leg wrap is used only as an adjunct external absorbent management device and does not replace primary medical care. It is specifically designed to reduce many of the safety issues associated with standard care and to test whether this Class 1 wound dressing can be self-managed by non-professional caregivers, thereby allowing more frequent dressing changes and reducing the clinical burden of daily skilled nursing visits solely to replace saturated dressings.

Early Termination Process/ Participant-requested withdrawal:

1. Participant chooses to stop participation for any reason.
2. Caregiver chooses to stop participation.
3. Participant withdraws consent.

Early Termination Process/ Safety-related withdrawal:

1. Increased skin breakdown judged by clinician.
2. New or worsening skin maceration.
3. Signs of localized infection (redness, warmth, purulent drainage).
4. Uncontrolled leakage causing failure of intended use.
5. Pain, numbness, or circulatory concern after application.
6. Allergic reaction or suspected material sensitivity.
7. Any unanticipated device-related adverse event.

Early Termination Process/ Clinical Necessity:

1. Treating clinician determines continued participation is not in the participant's best interest.
2. Participant requires hospitalization due to a worsening lower-extremity condition or any other condition that requires hospitalization.
3. Participant develops medical instability, making continued participation inappropriate.

Early Termination Process/Protocol noncompliance:

The participant may be withdrawn if the caregiver demonstrates an inability to apply or remove the investigational wrap in a manner consistent with training and safe study use.

RISKS AND ANTICIPATED BENEFITS:

Scientific Background with evidence-based information:

Overview: This clinical study evaluates the efficacy of a new nurse-developed product, the Disposable Leg Wrap (DLW), designed to address the 7 main challenges associated with traditional bulky gauze wraps used for managing highly exudative conditions such as lymphorrhea (also known as weeping edema).

Managing fluid associated with highly exudative leg conditions, such as lymphorrhea, commonly referred to as weeping leg edema, presents significant challenges that can substantially diminish the quality of life for affected individuals. This complexity also places considerable strain on healthcare systems, which often struggle to meet the needs of patients requiring frequent nursing interventions for dressing changes involving complex gauze wraps. Patient and family feedback frequently indicates that, despite daily care, their needs remain inadequately addressed, primarily due to intrinsic limitations of bulky gauze wraps.

Risks/problems with current care options:

1. The cumbersome nature of these wraps necessitates nursing visits every one to two days for dressing changes, raising concerns regarding the delegation of such tasks to non-professional caregivers due to care and safety issues.
2. The absorbent capacity of gauze materials is inherently limited, often leading to saturation before the next scheduled visit.
3. Cotton-based gauze is ineffective at wicking fluid away from the skin, which can lead to maceration and an increased risk of new wounds and infections.
4. The lack of adjustability in these wraps can lead to either excessive looseness, causing the wrap to slip down the leg, or excessive tightness, which may induce pain and create potential ischemic conditions as fluid dynamics evolve.
5. Gauze wraps hinder visual assessment of the wound or skin without requiring a complete dressing change.
6. There is often inadequate protection against fluid leakage through the dressing, leading to soiling of patients' clothing, furniture, bedding, and other personal items.

Additionally, the emotional impact of ongoing fluid leakage can be profound, with patients often expressing feelings of uncleanliness, anxiety, and shame. Family members and caregivers

frequently experience frustration, sadness, and helplessness as they witness their loved ones enduring this persistent challenge.

Possible Device-Based advantages:

1. The 1-piece design is relatively simple to apply. This may allow non-licensed caregivers to perform dressing changes with less technical complexity than that required for conventional multilayer absorbent lower leg dressings.
2. May reduce the time it takes to provide needed leg care. Preliminary performance testing has shown that a non-professional, after a 5-minute training session, was able to remove a dressing, cleanse the leg, and reapply the leg wrap in less than 5 minutes.
3. May improve containment of exudate (weeping fluid) between dressing changes, thereby reducing the problem of fluid leakage onto clothing, bedding, or the surrounding environment.
4. May reduce the use of multiple separate dressing components by integrating absorbent and securing functions into a single disposable wrap system.
5. May reduce dependence-related stress by enabling family or informal caregivers to assist more easily (and safely).
6. May improve sense of dignity by allowing dressing changes to occur more discreetly at home, and may decrease anxiety related to dressing failure, leakage, or odor, which can often occur between dressing changes.

In conclusion regarding possible benefits, for the purpose of this pilot study, we are evaluating the ability of the non-professional caregiver in a home setting to perform dressing changes independently after receiving standardized instruction. If the disposable leg wrap can be safely managed by trained non-professional caregivers, it may support more efficient use of the healthcare personnel resources while maintaining continuity of standard wound care practices. These potential advantages are exploratory and have not yet been established. The purpose of this pilot study is to evaluate usability and caregiver implementation under routine care conditions.

EQUITABLE ELIGIBILITY CRITERIA:

Inclusion criteria:

1. Adults (18 yrs or older) with lower extremity weeping edema requiring routine absorbent dressing changes.
2. Receiving standard care for chronic lower extremity weeping edema.
3. Residing in a setting where a non-professional caregiver is available and willing to perform dressing changes after instruction. Must be the same person receiving the initial instruction who provides dressing changes.

4. Must be able to express assent to participate in this study. If not legally decisional or physically unable to sign consent, the patient must have a legally authorized representative to review the information and sign the consent forms on their behalf.

Exclusion criteria:

1. Active infection requiring interventions beyond routine dressing changes.
2. Any wounds other than superficial blistering, which often accompany weeping edema episodes.
3. Known allergy or sensitivity to nonwoven, polymer-based leg wrap materials.
4. Clinical instability in which participation could interfere with medical treatment.
5. No available singular caregiver able to complete the study procedures.
6. Patients who live in a facility setting, unless a family member is willing and able to participate in this study.

Participants will be selected based on the presence of lower-extremity weeping edema requiring standard dressing management and on the availability of a nonprofessional caregiver who can perform dressing changes after instruction. Inclusion and exclusion criteria are based solely on clinical appropriateness, participant safety, and the ability to assess caregiver use of the disposable leg wrap. No participants will be excluded on the basis of gender, race, ethnicity, socioeconomic status, or other unrelated demographic characteristics.

OUTLINE OF INFORMED CONSENT PROCESS:

Engagement Process:

Potential participants will be contacted by authorized study personnel and provided verbal and written study information in a private, non-coercive setting.

Documentation and Waivers:

The informed consent process will include an opportunity for questions, assessment of participant understanding, and adequate time for voluntary decision-making prior to enrollment. Consent documentation will be maintained in accordance with IRB and institutional requirements. Any request for waiver or alteration of consent documentation will comply with applicable regulatory criteria.

Protection of Vulnerable Populations:

Additional safeguards will be implemented when working with potentially vulnerable populations to ensure that participation is voluntary and to protect against undue influence or coercion. Patient autonomy is maintained through the inclusion criteria, which require that all

patients must be able to "assent" to their participation in the Leg Wrap study. In some cases, a legal representative may need to sign the consent paperwork on behalf of the patient.

DATA AND SAFETY MONITORING PLAN:

Safety Data Points:

1. Ongoing care: Skin assessments will be performed per the care plan already in place for each patient, which traditionally assesses for and documents any clinically significant changes. During the study, the assigned RN case manager can visit the patient per the usual schedule, open the wrap to assess the skin, and then close the wrap when the assessment is finished. This allows for ongoing monitoring without interfering with the study itself, as the assigned non-professional caregiver is responsible for providing necessary leg care and dressing changes.

2. Adverse events plan: Although the Leg Wrap disposable wrap is made from well-known, tested, and FDA-approved materials, if the patient or caregiver suspects that the device is causing harm, such as skin sensitivity or any other perceived problem, the caregiver will contact [redacted] 24/7 to report any issues or concerns. The patient chart will include information about Leg Wrap study participation, including the e-mail address for the Leg Study group overseeing this study, for follow-up evaluation and next steps.

3. Ongoing Oversight: The Home Health and/or Hospice staff will retain all usual roles and responsibilities in regard to participants in this study. They will be aware of the research being conducted, and will defer leg hygiene and dressing changes to the assigned non-professional caregiver during the 3-6 days of this study. The P.I. will be monitoring all study activity, ensuring correct patient selection, supporting the research study RN and acting as a liaison and contact for home health or hospice case management personnel.

PROTECTING PARTICIPANT PRIVACY AND DATA CONFIDENTIALITY:

1. Secure Data Handling: The P.I. will obtain the 4-digit patient identification code from the study RN, which is on the Study Survey form for each case. This code will replace the name on the survey, which will be sent in the pre-addressed, postage-paid envelope to the Leg Wrap PO Box address. This safeguards the P.I. from potential exposure if the mail is intercepted. The reason we chose a paper survey is to remove barriers associated with electronic surveys, which we anticipate may be difficult for some participants and/or caregivers to manage.

2. Details of data storage and transfer: EPIC integrated study support/documentation tools have yet to be specifically defined but are likely to follow the same or similar processes and procedures used in standard hospital research study protocols.

SPECIFIC REGULATORY DOCUMENTATION:

1. FDA status: No FDA clearance or exemption pursued.

The Leg Wrap is intended to assist with the containment and management of lower-extremity exudate associated with weeping edema. This device is non-powered, externally applied, and does not deliver medication, compression, thermal energy, or biologic treatment. The polymer-based materials used in the construction of this wrap are already commonly used in the wound care space. While there is recognition of unforeseen consequences with any newly developed product in contact with fragile skin, evidence strongly suggests that it is safer than the current standard of care, which uses gauze wrapping around the lower leg to secure various absorbent products, such as ABD pads, which have been known to have a myriad of problems (refer to the "addendum" page which outlines the problems with current care options). The device is sterilized and tested twice in separate labs for contamination, before and after EO sterilization. (Lab results will be included in the "additional information" section of this report. For these reasons, we are hopeful that the Leg Wrap can be considered a minimal-risk device for this small pilot study.

PARTICIPANT-FACING MATERIALS:

1. Front and back of insert included with each individually packaged Leg Wrap
2. Consent/waiver form
3. Survey Questionnaire
4. QR link for Leg Wrap teaching video