CLINICAL INVESTIGATION PLAN (CIP)

Appendix B

INVESTIGATIONAL DEVICE:

Exufiber Ag+

INVESTIGATION TITLE:

A clinical investigation to study the effect of Exufiber Ag+ and other gelling fibre dressings on wound exudate and bioburden in medium to high exuding wound.

SITE NO:

SUBJECT NO:

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. The Web site will also include a summary of the results. You can search this Web site at any time.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, “you” always refers to the subject, yourself.

PATIENT INFORMATION AND CONSENT FORM

We would like to ask you to participate in a research investigation to be conducted by Dr. XXXX.

A. The Purpose of the Investigation

The investigation is being carried out to investigate the impact of Exufiber Ag+ and other gelling fiber dressings on handling wound exudate, bioburden (number of bacteria) and possible associated molecular biomarkers (indicators for infection). Currently, most patients who have problems with wounds have problems with their dressings and healing. Delayed healing is often caused by bacteria, in other words wound infection. This is a research project and there is no guarantee that your wound condition will be improved but your progress will be followed closely. In approximately 105 patients in the US, male or female, aged 18 and above with medium to high exuding wounds will be included in the investigation.

B. Description of the Investigation

1. At the initial interview, the doctor/nurse will ask you questions about your health to make sure you do not have any serious health problems or other issues that might make completing the investigation dangerous or difficult. You will then have a physical

examination, your vital signs will be measured,your wound will be inspected at and you will be assigned to one of three dressings (Exufiber®Ag+, Exufiber® or Aquacel™Ag Extra™).

2. You will be treated with the dressing for 4 weeks or earlier if the wound is dry or healed. The dressing will be changed according to the schedule that you and your doctor/nurse agree upon, at least every 7 days or earlier if needed. At each dressing change the doctor/nurse will ask you some general questions about your wound and your health and take photographs of the wound.

3. The maximum duration of the investigation is 4 weeks (5 scheduled visits). There will be approximately 105 subjects across 10-15 sites in the US.

4. The dressings are 510(k) cleared, which means that they are approved for sale and use in the US.

C. Foreseeable Risks and Discomforts

In previous investigations, the dressing has been found to be safe and well tolerated. It is possible that you might experience some discomfort when the dressing is changed.

Other rare side effects are possible, including: allergic reactions, maceration, prolonged wound healing, infection, discolouration, sensitisation, skin irritation. There may also be other currently unforeseeable risks, which cannot be predicated at the present time. You are encouraged to report anything that is troubling you.

If any new information becomes available during the investigation, that could influence your decision to participate, you will be informed.

D. Potential Benefits

You may benefit by experience less pain, trauma and better healing with the new dressing, the knowledge about exudate management, bacteria and indicators for infection generated from this investigation may contribute to better wound treatment in future patients.

E. Alternative Therapy

As an alternative to participation in this investigation, you may continue with the dressing/treatment regimen you use today. You will be followed up as is standard practice. You can ask your doctor/nurse about different treatments that may be available to you

F. Questions and/or Termination of Participation

Your participation in the investigation is voluntary. You may refuse to take part or may decide to stop at any time. This will not affect your relationship with the doctor/nurse, who will give you the best treatment he/she can offer. Also, your doctor may decide that you should discontinue participation in the investigation if there is poor protocol compliance, if you experience an adverse event considered unacceptable or your doctor decides that it is in the your best interest, or if the sponsor decides to terminate the investigation for any reason.

G. Confidentiality

The information collected during the investigation will be stored in a computer but neither your name nor your initials will be revealed. Only your doctor will know that the information is related to you. The results of the investigation may be published in the medical literature, but your identity will not be revealed.

Photographs of the wound will not reveal your name and will be kept confidential. Photographs taken during the investigation may be used for educational, informational, and marketing purposes, as well as for general advertising, publicity, and promotional purposes.

Authorised individuals representing government bodies and/or the sponsoring company will look at your medical records (the data that are related to your wound disease), without violating confidentiality, to check that the investigation has been properly performed. This can only be done with your permission, and it is therefore understood that by signing the Consent Form you are grant this permission.
The IRB is the committee that reviewed this research project to help ensure that the rights and welfare of the participants are protected and that the investigation is carried out in an ethical manner. Mölnlycke Health Care AB (study sponsor), the U.S.Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (DHHS) may require a copy of the records.

H. Confidentiality and Authorization to Use and Disclose Personal Health Information

A federal regulation called the “Health Insurance Portability and Accountability Act” (HIPAA) describes how your personal health information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This investigation can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state, and federal laws. Personnel from the following organizations may examine your study records: the sponsor (Mölnlycke Health Care AB); personnel associated with this study; regulatory agencies, such as the Food and Drug Administration (FDA); and the IRB . Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal information that may be used and includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth, or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, your records may not be available until the investigation has been completed.

You may, by written notice to the study doctor, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization has no expiration date.

I. Compensation

You do not have to pay for any study-related procedures or treatments. The study dressings will be provided for use at no cost by the sponsor (Mölnlycke Health Care). Other products that would normally be used as part of the study sites standard of care are already available at the study site and will be charged to your hospital bill, as it would be normally.

Ask your doctors to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects.

Compensation for reasonable medical expenses associated with the treatment of any side effect directly related to the study dressings including hospitalization, if necessary, will be provided by the sponsor (Mölnlycke Health Care), providing the study product has been used properly during the study. If, as a result of your participation, you experience direct physical injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be provided at no cost to you. However, payment for medical conditions that are not related to the study will not be offered .

If you are injured directly by your participation in the investigation the sponsor company will compensate you in accordance with the laws of XXXX. The sponsor company is insured in this respect.

No other form of compensation is offered.

In case of investigation-related injury, please contact the study doctor.

J. Request for More Information

Any questions you have regarding the study or your rights as a subject in the study will be answered. If you have any questions about this research project; are injured or become ill as a result of this study; or if you have questions, concerns, or complaints about the research, the study doctors in charge can assist you.

The study doctors listed below should be contacted in case of an emergency:

Name: _____

Address: XXXXX

XXXXX

24-hour emergency number (XXX) XXX-XXXX.

If you have any questions about your rights or related concerns as a research subject, or if you have questions, concerns, or complaints about the research, you may contact:

IRB Name: _____

Address XXXXX

City, State, Zip XXXXX

Phone: XXXXX

E-mail: _____

_____ IRB is a group of people who perform independent review of research.

_____ IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact _____IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Review and approval of this study by the _____IRB is not an endorsement of the study or its outcome.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will be given a copy of this signed and dated consent form.

Consent

I have read and have been given an explanation of the study. I have been given the opportunity to ask any questions about the study which I may have, and all my questions have been answered to my satisfaction. I am signing this form freely and without being pressured. I voluntarily consent to participate in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up my legal rights.

WRITTEN CONSENT

INVESTIGATION CODE: ExufiberAg+01 **SUBJECT NO.:**

PHOTOGRAPH INFORMATION	**Yes**	**No**
I give my permission to the sponsor of this investigation, Mölnlycke Health Care AB, to use photographic images taken during the investigation for educational or informational purposes or for general advertising, publicity and promotional purposes. The photographic images will be identified only by subject code and my name will not be used	☐	☐
If you do not consent using your photographic images for the purpose stated above, you will still be able to participate in this investigation		

I, _____

(Patient's name, block letters)

have read the attached information, and have discussed what the investigation concerns with

Principal Investigator _____

(Principal Investigator name, block letters)

I understand that my participation is voluntary and I understand what the investigation involves

PATIENT/WITNESS I hereby voluntarily sign to indicate participation in the investigation.

_____

(Date) (Signature)

Principal Investigator I have explained the nature and purpose of the investigation to the patient designated above.

_____

(Date) (Signature)