Clinical investigation title:
Clinical functional assessment of moisture sensor on wound dressing

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Investigational device:
Wound dressing DryMax Extra Soft (size 10x10 cm, 10x20 cm or 20x20 cm) with a moisture sensor (Absorbest Fuktsensor) on top.

Study type:
Explorative study of function of a moisture sensor on top of a superabsorbent wound dressing on exuding leg ulcers.

Sponsor:
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1 Summary of Clinical investigation plan (CIP)

The original CIP is written in Swedish. This is a summary of the CIP in English.

1.1 Objectives

The primary objective:

To study which of the investigational devices, Variant A and Variant B, that gives a correct activation of the display in relation to the level of saturation of the wound dressing.

The secondary objectives:

To study the consequences in case the dressing has been changed too late. In these cases:

- Have there been occurrence of leakage and how has that affected the wound status and surrounding skin?
- Have there been occurrence of maceration and how has that affected the wound status and surrounding skin?

To study the usability

- How often are there use errors, such as incorrect dressing application?

1.2 Design and endpoints

Patients with exuding leg ulcers were included from two different study sites for the clinical investigation. The clinical investigation is a small, explorative study which aimed to include 6 patients. To complete the study each patient underwent three dressing changes with the investigational device. Both study product versions, Variant A and Variant B, were used on each patient, either in order A-B-A or B-A-B. Amount and type of exudate might change over time, in this way the same variant is used at start and end to detect any changes in results. The aim was to get as many observations from Variant A and Variant B respectively.

Between dressing changes the patients were instructed to monitor the display and note if a blue drop (display activation) appeared. At each dressing change the patient and the caregiver checked the display for activation, weighed the dressing, recorded the wound status and eventual incidents.

1.3 The clinical investigation hypothesis or pass/fail criteria

The activation of the display in relation to the level of saturation of the wound dressing is determined by weighing the dressing after use which is then checked against the specified intervals in the Table below. The level of saturation is deemed to be in correct interval if the weight of the study product (Absorbest Fuktsensor + DryMax Extra Soft) is in the interval 11-26 g for 10x10 cm, 17-62 g for 10x20 cm and 26-109 g for 20x20 cm.

Table 1. Intervals to determine saturation level of the used dressing. Weight includes dressing dry weight and absorbed liquid

Dressing size	Changed too early	Interval for correct change	Changed too late
	Weight of dressing [g]		
10x10 cm	<11	11-26	>26
10x20 cm	<17	17-62	>62
20x20 cm	<26	26-109	>109

Since the study is small, explorative and observational, no statistics are relevant to calculate. The study does not aim to achieve statistical significance between Variant A and Variant B, but to collect data which should form the basis for a comprehensive assessment of the function of the different variants.

1.4 Concomitant medications/treatments

The study product was limited to be used as a primary dressing. However, wound care products on the surrounding skin was allowed and the dressing was fixated by appropriate methods.

Since a large proportion of exuding leg ulcers are treated with compression therapy, this treatment was allowed in combination with the study product. The study was not designed to give evidence if the sensor activation is different with or without the use of compression therapy, but the use of compression therapy is documented for knowledge and discussion.

1.5 Inclusion and exclusion criteria's

All patients had to fulfil the inclusion criteria, not have any of the exclusion criteria and give written informed consent. All patients were informed that the participation was voluntary, and they had the right to withdraw whenever wanted.

Inclusion criteria:

- Male or female, ≥18 years.
- Presence of moderate to high exuding leg ulcer, according to the clinician's assessment.
- The wound is deemed suitable for treatment with study product.
- The participant has given a written informed consent to participate in the study.

Exclusion criteria:

- Known pregnancy at the inclusion visit.
- Prisoner.
- Bleeding from the wound surface.
- The leg ulcer that is relevant for inclusion in the study is larger than 16x13 cm.
- Known or suspected hypersensitivity to the study products or its components. Components of DryMax Extra Soft: Polypropylene nonwoven outer cover, sodium polyacrylate and viscose-polyester as core material. Hot-melt glue seals the outer cover. Components in Absorbest Fuktsensor: PET-plastic in sensor and presence of small amounts of carbon, zinc, manganese dioxide, silver, conductive colour inks and electrolyte solution.
- Mental inability, reluctance or language difficulties that cause difficulties in understanding the meaning of participating in the study.
- The wound is infected.
- Illness or treatment of an indication other than the wound and which, according to the study personnel, can affect the wound treatment, the study and/or the dressing.

1.6 Data quality assurance

The clinical investigation was monitored by an external partner to assure that correct information was given in the filled in forms, e.g. the clinical research forms.

1.7 Ethical considerations

The clinical investigation has been performed in accordance with the International Standard EN-ISO 14155:2011 and the Declaration of Helsinki. Approval for the clinical investigation was given by the local ethics committee and the Swedish Medical Products Agency and all patients included filled in an informed consent before start.

1.8 Amendments

For detailed descriptions of the amendments to the first version of the clinical investigation plan (CIP), see respective version. The main updates and reasons for updates are described here:

- **Version 2.0:** Updated according to requests for supplements by the Swedish Medical Products Agency to clarify some sections in the text.
- **Version 3.0:** Small updates before start of clinical investigation to clarify some sections in the text. Addition of signature page for the principal investigator.
- **Version 3.1:** Update of the acceptance limit for determination of correct change intervals. This was done before start of clinical investigation.
- **Version 4:** Inclusion of one more size, 20x20 cm, of the dressing DryMax Extra Soft used in the clinical investigation. The expected duration of the study changed from 6 months to 18 months, since the first 8 months included only 1 patient.
- **Version 5:** Inclusion of one more study centre; S2Clinic in Linköping to the clinical investigation.