Trial Full Title	Multicenter, randomised in parallel groups, controlled study to compare performance and safety of Suprasorb®X+PHMB Pro with Suprasorb® X+PHMB dressing in treatment of infected venous leg ulcers
Study acronym	Suprasorb®X+PHMB
SAP Version	FINAL v. 1.0
SAP Version Date	10 September 2025
Study Plan Version	Final Version 1.1
Study Plan Version Date	14 August 2025
Plan Prepared By	Teresa Szenk
Plan Checked By	Agnieszka Segiet-Święcicka

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ABBREVIATION LIST

ADE	Adverse device effect
AE	Adverse event
ATC	Anatomical Therapeutic Chemical Classification System
ABPI	Ankle brachial pressure index
CDC	Centres for Disease Control and Prevention
CDL	CleanDataLabs
DD	Device Defficiency
e-CRF	Electronic Case report form
EOT	End of Treatment
FAS	Full analysis set
ICF	Informed consent from
ICD-11	International Classification of Diseases, 11th Revision
NRS	Numeric rating scale
PPS	Per protocol set
N	Population size
PMCF	Post-market Clinical Follow-up
QoL	Quality of Life
SAS	Safety analysis set
SADE	Serious adverse device effect
SAE	Serious adverse event
SD	Standard deviations
SAP	Statistical Analysis Plan
TFL	Tables, Figures, and Listings
TILI	Therapeutical Index for Local Infections
VLU	Venous leg ulcer

1 INTRODUCTION

Statistical Analysis Plan (SAP) has been developed based on Study Plan version Final 1.1 dated 14 August 2025.

SAP describes planned statistical analyses of the data gathered in this study. Details of the planned TFLs are presented in the Sections 14. The purpose of this SAP is to ensure that the data listings, summary tables and figures that will be produced, and the statistical methodologies that will be used, are complete and appropriate to allow valid conclusions regarding the study objectives.

CDL (Clean Data Labs) will perform the statistical analyses for all study objectives and is responsible for the production and quality control of relevant tables, figures, and listings (TFLs).

The final analysis will be conducted by CDL after all subjects complete the study or terminate early from the study, based on the data extracted from the database after database closure and external data (W.H.A.T. results, sub-bandage pressure and leg circumference measurements results). The interim analysis will be conducted by CDL after 75 randomized patients complete the study or terminate early from the study, based on the data extracted from the database after partial database closure and external data (W.H.A.T. results, sub-bandage pressure and leg circumference measurements results). All data available in the CRF and signed by the investigator will be transferred for analysis.

2 STUDY DESCRIPTION & STUDY DESIGN

Study design

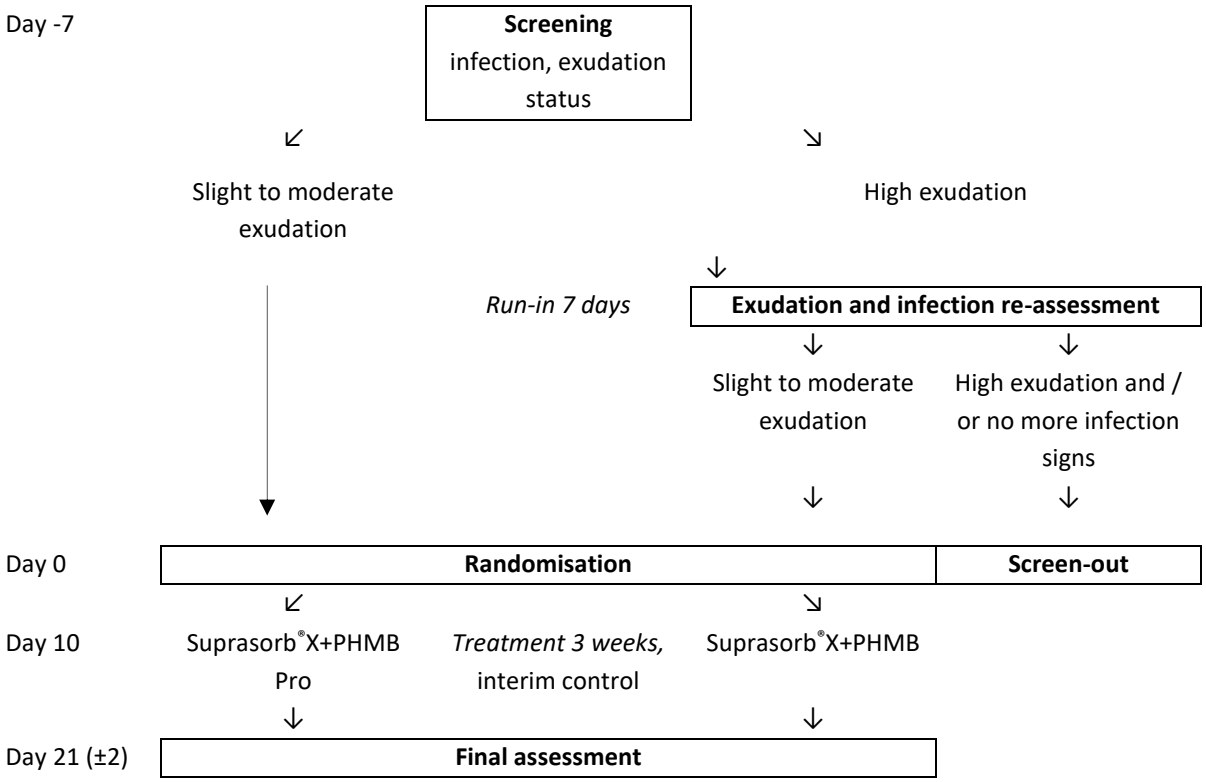
This PMCF clinical investigation (post market clinical-follow-up) will be conducted as multicenter, randomized in parallel groups, open-label, controlled study to compare the performance and safety of Suprasorb® X+PHMB Pro with Suprasorb® X+PHMB dressing in treatment of infected venous leg ulcers.

During the screening eligible patients with slight or moderate wound exudation will be randomly assigned to treatment with either Suprasorb®X+PHMB Pro or Suprasorb®X+PHMB. The patients who fulfil all other eligibility criteria but have high level of wound exudation will enter a 7-days run-in period, during which they will receive the appropriate treatment. Then they will be re-assessed and in case they still fulfil all eligibility criteria, and the exudation decreased at least to a moderate level, they will be randomised to the study. In case the exudation would not decrease within this period or other eligibility criteria are not met anymore, they will be screened out.

Upon randomisation, all patients will receive the assigned dressing for 21 (±2) days, or till the complete epithelialization, if it occurs earlier. After 3 weeks of treatment with Suprasorb®X+PHMB Pro or Suprasorb®X+PHMB, all patients will complete the study.

During the study participation, selected parameters of the wound will be assessed at Baseline, Interim Visit, and EOT visit. In addition, dressing changes may be performed in-between on as needed basis.

Study schema



Study population

150 adult patients with infected venous leg ulcer will be randomised in the study in a 1:1 ratio to each treatment group (75 in each group), a drop-out rate of 5% is expected. To get this number, screening and inclusion of up to 200 patients is planned. Full list of inclusion and exclusion criteria is presented in Study Plan.

Sample size

Enrolment of 150 patients, under assumption of 5% drop-out rate, will allow to estimate the percentage of patients with selected level of maceration at the end of treatment by the study arm with precision equal or greater (i.e. width of 95% confidence interval less than or equal to) 24 percentage points for percentage of 50% and increasing (i.e. decreasing width of 95% confidence interval) for percentages lower than and higher than 50%.

Study flowchart

Procedure / Task	Screening	Baseline	Interim visit	Additional visits (VA1, VA2, etc.)	Final Visit / Early Termination Visit*
Timeline	(Day – 7)	Day 0	Day 10 ± 2	Each dressing change	Day 21 ± 2
Inclusion/exclusion criteria	✓	✓			
Informed consent	✓				
Assessment of wound exudation status ** +	✓	✓	✓		✓
Measurement of leg circumference **	✓	✓	✓	✓	✓
Optional, in case of a high-exuding wound: start of 7 days run-in period	✓				
Pressure data read-out **	✓	✓	✓	✓	✓
Demographics		✓			
Medical history		✓			
Wound history and previous treatment		✓			
Infection signs assessment (TILI and CDC score) **+	✓	✓	✓		✓
Maceration grade assessment #		✓	✓		✓
Pain assessment (NRS) after dressing removal +		✓	✓		✓
Wound cleaning / debridement **	✓	✓	✓	✓	✓
Wound photograph #		✓	✓		✓
Wound size and depth #		✓	✓		✓
Wound bed status #		✓	✓		✓
Surrounding skin assessment #		✓	✓		✓
Randomisation		✓			
Application of assigned study dressing		✓	✓	✓	
Adverse events	✓	✓	✓	✓	✓
Concomitant treatment***	✓	✓	✓	✓	✓
Device deficiency	✓	✓	✓	✓	✓
Wound Quality of Life **	✓	✓	✓		✓
Complete healing assessment			✓		✓
Global assessment investigator****					✓
Global assessment patient					✓

* Some of the activities may be not applicable for patients who have complete epithelialization

** If screening and baseline visits are performed on the same day, the procedure to be completed only once
*** Only concomitant medication which is prescribed for the wound treatment or may have effect on the wound treatment in general should be recorded (see Annex 1)
**** By an on-line questionnaire upon completion of the last patient at each site (see Annex 2)
+ To be assessed just after taking out the wound dressing
# To be assessed after wound cleaning but before debridement

3 OBJECTIVE OF THE STUDY

Evaluation of performance and safety of Suprasorb®X+PHMB Pro in the treatment of infected venous leg ulcers in comparison to Suprasorb®X+PHMB.

4 ANALYSIS POPULATIONS

Full analysis set (FAS = Intention-to-treat): includes all patients randomised, independently of the real treatment they got, following the intent-to-treat principle (i.e. patients in FAS will be assessed by assigned treatment).

Safety analysis set (SAS) includes all patients randomised and treatment started, patients will be analysed in SAS by treatment actually received.

Per protocol set (PPS) includes all patients randomized who were compliant to the procedures as defined by the PMCF plan.

The following patients will be excluded from the per-protocol analysis:

- Patients not meeting the inclusion/ exclusion criteria.
- Initiation of study procedure prior to obtaining informed consent.
- No available measurements of the primary variable/endpoint.
- Incomplete treatment, i.e. if treatment is discontinued due to complications or an undesirable event or for other medical reasons
- Change of assigned treatment to the other group without medical reason.

5 ENDPOINTS AND COVARIATES

5.1 PRIMARY ENDPOINT

1. Rate and severity of maceration during 3 weeks of treatment with Suprasorb®X+PHMB (Pro) (by the investigators' assessment as well as by an independent assessment of the wound photos).

5.2 SECONDARY ENDPOINTS

1. Wound area changes over time (by the investigators' assessment as well as by an independent assessment of the wound photos).

2. Change of necrotic and fibrinous and granulation tissue rate in the wound bed (by an independent assessment of the wound photos).
3. Change of wound infection status during the study (by a CDC definition and a TILI score).
4. Product safety (assessed by rate of product-related complications).
5. Change of wound exudation and presence of peri-wound oedema (by the investigators' assessment).
6. Change in patient's pain (measured by NRS scale).
7. Product usability (assessed by means of user and patient questionnaire for both Suprasorb®X+PHMB (Pro) and Rosidal 1C).
8. Change in patient's quality of life (assessed by means of Wound QoL-17 scale).
9. Oedema reduction (by measurement of limb circumference).
10. Sub-bandage pressure levels retention (difference of the pressure levels, measured at the time of application and before the next dressing change).

5.3 SUBGROUPS AND COVARIATES

As a part of exploratory analyses, efficacy analyses will be performed in subgroups by maceration grade at the study entry.

6 MISSING VALUES HANDLING

No missing data imputation will be applied, data will be analysed as available. The number of missing observations will be reported in respective tables.

7 STATISTICAL METHODS

7.1 GENERAL INFORMATION

Data will be analysed using descriptive statistical methods. No formal hypothesis testing will be performed. No formal comparisons between study arms will be performed. 95% confidence intervals will be reported for primary endpoint outcome measure.

Collected data will be summarized using descriptive statistics by study arm (Suprasorb®X+PHMB Pro or Suprasorb®X+PHMB) and by time point of assessment, if applicable. If applicable, changes in relevant parameters (e.g. pain or questionnaires for user satisfaction) from baseline will be calculated and summarized.

Descriptive statistics will be presented as number of non-missing observations and relative frequency for categorical variables and as number of non-missing observations, mean, and standard deviation, median with minimal and maximal value for continuous variables. Number of missing observations will be reported for each variable.

Individually derived parameters and appropriate summary statistics will be reported to three significant figures. N will be reported as a whole number and percentage will be reported with one decimal place. Minimum and maximum values will be treated as an observed parameters and reported with the same number of decimal places as received values of the measured parameter, while values of mean, SD, and median will be reported with one decimal place more than received values of the measured parameter.

Unless otherwise specified, baseline will be the last non-missing observation before the start of the study treatment (i.e. before application of the assigned study dressing), which is expected to be Day 0 before the first product application.

All efficacy statistical analyses will be conducted for FAS (primary analysis) and PP (sensitivity analysis) sets separately, and safety analysis will be conducted for SAS set. Baseline characteristics will be summarized for FAS population.

A level of statistical significance alpha is set at 0.05, what corresponds to the two-sided 95% confidence intervals.

7.2 SPECIFIC INFORMATION ON DATA ANALYSIS

7.2.1 Subject disposition, withdrawals and study completion

Data on subjects' disposition will be summarized in table, following summaries will be reported: number of subjects screened (i.e. signed ICF), number of subjects qualified to the study at screening, number of subjects included in run-in period, number of subjects qualified to study after run-in period, number of subjects included in the each analysis set, number and percentage of patients who completed the study according to the protocol among FAS population, number and percentage of patients who dropped out of the study prematurely among FAS population along with a summary of the reasons for premature termination of the study. A listing of data on the assigned product, analysis sets inclusion, dates of ICF signature, dates of visits, and date of study end, data on study completion and reason for premature termination, and eligibility status will be prepared. Above summaries will be prepared for all patients enrolled, overall and by study arm (assigned product).

7.2.2 Demographic and clinical baseline data analysis

Descriptive statistics for demographics and baseline characteristics will be presented, including:

- demographics (gender, age, weight, height, BMI (calculated as weight [kg]/height^2 [m] and rounded to two decimal places)),
- anamnesis (reported diagnoses will be coded in ICD-11 dictionary in terms of name and code; data will be summarized in terms of presence of any relevant comorbidity and prevalence of relevant comorbidities by ICD-11 name),
- relevant concomitant medication (reported medications will be coded in ATC dictionary (2025) in terms of ATC codes and names for levels 3 and 5; data will be summarized in terms of use of any relevant concomitant medication and prevalence of use of relevant concomitant medication by ATC level 3 name and ATC level 5 name),

- description of the wound before study dressing application (at baseline): wound duration, calculated as difference in dates between wound onset and date of ICF sign/30 [months], wound localization,
- ABPI at screening,
- run-in period presence and, if happened, results (use of wound cleaning/debridement, used dressings, number of dressing changes).

Listing of demographic data will be provided. Listing of relevant concomitant diseases will be provided, including name of disease and date of first detection and date of healing. Listing of relevant concomitant medications and treatment will be provided, including tradename/type of therapy, indications, dosage with unit, application type, frequency and start and end date.

Above summaries will be prepared for FAS population, overall and by study arm. Summary of run-in period results will be prepared for all patients from FAS who started run-in period, overall.

7.2.3 Primary endpoint analysis

Primary endpoint is to assess rate and severity of maceration during 3 weeks of treatment with investigational device Suprasorb®X+PHMB Pro in comparison to comparative device Suprasorb®X+PHMB. Percentage of patients with maceration at each of 4 levels of the scale at V1, V2, and V3, as well as change from baseline (V1) to interim visit (V2) and to end of treatment at final visit (V3) (presented in terms of shift between results, i.e. in form “result at V1 -> result at VX”) will be reported, overall and by study arm, with corresponding two-sided 95% confidence intervals.

Analysis will be performed separately for the investigators’ assessment as well as for an independent assessment of the wound photos.

Bar plots will be provided to present the distribution of maceration scores in time.

Primary endpoint will be assessed in FAS (primary analysis) and PPS (sensitivity analysis) populations.

7.2.4 Secondary endpoints analysis

Secondary efficacy endpoints will be assessed in FAS (primary analysis) and PPS (sensitivity analysis) populations. Safety will be assessed in SAS population.

1. <u>Wound area change over time (by the investigators’ assessment as well as by an independent assessment of the wound photos)</u>
   Following measures for the assessment of changes of wound area will be collected or derived, based on the wound size measured by investigator:
   - wound length [cm],
   - wound width [cm],
   - wound depth [cm],
   - estimated wound area [cm2], calculated as wound width [cm] x wound length [cm].

   and based on the W.H.A.T. measurements:
   - wound length [cm],
   - wound width [cm],
   - wound depth [cm],

- wound area [cm2].

Descriptive statistics will be presented for above measures of wound area by time point of assessment (baseline visit (V1), interim visit (V2), final visit (V3)), overall and by study arm. Descriptive statistics will be presented for change from baseline (V1) to interim (V2) and to final visit (V3) in above measures of wound size, overall and by study arm.

Box-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measures in time.

2. Change of necrotic & fibrinous & granulation & epithelialized tissue rate in the wound bed (by an independent assessment of the wound photos)

Following measures for the assessment of changes in wound bed tissue composition will be collected or derived, based on the wound size measured by investigator:

- percentage of wound area covered by necrotic tissue [%],
- percentage of wound area covered by fibrinous tissue [%],
- percentage of wound area covered by granulated tissue [%],
- percentage of wound area covered by epithelialized tissue [%],
- derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]),
- derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]),

and based on the W.H.A.T. measurements:

- wound area covered by necrotic tissue [cm2],
- wound area covered by fibrinous tissue [cm2],
- wound area covered by granulated tissue [cm2],
- wound area covered by epithelialized tissue [cm2],
- derived parameter: wound area covered by necrotic or fibrinous tissue [cm2] (sum of wound area covered by necrotic tissue [cm2] and wound area covered by fibrinous tissue [cm2]),
- derived parameter: wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of wound area covered by necrotic tissue [cm2] and fibrinous tissue [cm2] and granulated tissue [cm2]),
- percentage of wound area covered by necrotic tissue [%],
- percentage of wound area covered by fibrinous tissue [%],
- percentage of wound area covered by granulated tissue [%],
- percentage of wound area covered by epithelialized tissue [%],
- derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]),

— derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]).

Descriptive statistics will be presented for above measures of wound bed tissue composition by time point of assessment (baseline visit (V1), interim visit (V2), final visit (V3)), overall and by study arm. Descriptive statistics will be presented for change from baseline (V1) to interim (V2) and to final visit (V3) values in above measures of wound bed tissue composition, overall and by study arm.

Box-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measure in time.

3. Change of wound infection status during the study (by CDC definition and TILI score)
Descriptive statistics will be presented for wound infection status during the study (by CDC definition and TILI score), by time point of assessment (screening (V0), baseline visit (V1), interim visit (V2), final visit (V3)), overall and by study arm.
Descriptive statistics will be presented for change from baseline (V1) of wound infection status during the study by time point of assessment (change from baseline at interim (V2) and at final visit (V3)), overall and by study arm.

Bar-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measure in time.

4. Product safety, assessed via the frequency and character of device deficiencies (DDs), adverse events (AEs), serious adverse events (SAEs), adverse device effects (ADEs), and serious adverse device effects (SADEs).
Safety will be assessed in SAS population.

Reported adverse events will be coded using IMDRF coding dictionary release no. 2025 or later in terms of level 1 and level 2 codes (level 3 codes if applicable). Adverse device effects (ADEs) will be defined as all AEs assessed as related to the use of investigational medical device, i.e. with relationship to study procedure or study product assessed by investigator as certain, probable/likely, possible or missing data (i.e. differently than unlikely, conditional/unclassified, unassessable/unclassifiable).

All AEs captured in the database will be listed in by-subject data listings.

Overall summary of reported AEs will be prepared: the total number of events, number and percentage of subjects who experienced any AEs, any serious AEs, any ADEs, and any serious ADEs, overall and by study arm. Reported AEs, SAEs, ADEs, and SADEs will be summarized in terms of seriousness, severity, relationship to study procedure and study product, action taken, and outcome, overall and by study arm.

Incidence and counts of AEs, SAEs, ADEs, and SAEDs will be summarized by level 1 and level 2 codes, overall and by study arm. If a subject has more than one occurrence of the same level 2 code, then the level 2 code will be counted only once for that subject under the level 1 code for which it was experienced.

All device deficiencies captured in the database will be listed in by-subject data listings. Overall summary of device deficiencies will be prepared: the total number of events, number and percentage of subjects who experienced any device deficiencies, overall and by study arm. Reported device deficiencies will be summarized in terms of potential complications, overall and by study arm. Incidence and counts of device deficiencies will be summarized by device deficiency description, overall and by study arm. If a subject has more than one occurrence of the same device deficiency description, then the description will be counted only once for that subject.

5. Change of wound exudation and presence of peri-wound oedema (by the investigators' assessment)
   Descriptive statistics will be presented for wound exudation (wound exudation status and character of wound exudation) and presence of peri-wound oedema (supported by other measures of surrounding skin assessment, i.e. presence of erosion, maceration, dryness/scaling, oedema, redness, moist, other), by time point of assessment (screening (V0) (for wound exudation only), baseline visit (V1), interim visit (V2), final visit (V3)), overall and by study arm.
   Descriptive statistics will be presented for change from baseline of wound exudation status (in terms of shift between results) and for change from baseline (V1) in presence of peri-wound oedema (in terms of shift between results) by time point of assessment (change from baseline at interim (V2) and at final visit), overall and by study arm.

   Bar-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measure in time.

6. Change in patients' pain (measured by NRS scale)
   Descriptive statistics will be presented for patients' pain (measured by NRS scale) measured in point scale, by time point of assessment (baseline visit (V1), interim visit (V2), final visit (V3)), overall and by study arm.
   Descriptive statistics will be presented for change from baseline in patients' pain (measured by NRS scale) by time point of assessment (change from baseline (V1) at interim (V2) and at final visit (V3)), overall and by study arm.

   Box-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measure in time.

7. Product usability (assessed by means of user and patient questionnaire for both Suprasorb®X+PHMB (Pro) and Rosidal 1C)
   Descriptive statistics will be presented for product usability (assessed by means of user and patient questionnaire for both Suprasorb®X+PHMB (Pro) and Rosidal 1C; patient questionnaire data comes from eCRF, user questionnaire data comes from external application), overall and by study arm.

8. Change in patient's quality of life (assessed by means of Wound QoL-17 scale)
   Data on responses in Wound QoL-17 scale are summarized in the following way: answers to each item (1-17) are coded with numbers (0='not at all' to 4='very much'). A Wound-QoL-17 global score is computed by averaging all items (1-17). A global score can only be computed if at least 75% of the items have been answered (i.e., at least 13 in 17 items are valid). In addition, subscales of the Wound-QoL can be calculated by averaging following items (only if no more than 1 item of the subscale is missing):
   1. Subscale 'Body': Items #1 to #5.
   2. Subscale 'Psyche': Items #6 to #10.
   3. Subscale 'Everyday life': Items #11 to #16.
   Item #17 does not belong to either of the subscales.

   Descriptive statistics will be presented for patient's quality of life (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday", as well as responses for each item), by time point of assessment (screening (V0), baseline (V1), interim (V2), and final (V3) visit), overall and by study arm. Descriptive statistics will be presented for change from baseline (V1) of patient's quality of life (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday") by time point of assessment (change from baseline (V1) at interim (V2) and at final (V3) visit), overall and by study arm. Descriptive statistics will be presented for change from screening (V0) to baseline (V1) of patient's quality of life (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday") for the subjects who completed run-in period, overall.

   Bar-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome measure in time.

9. Oedema reduction (by measurement of limb circumference)
   Descriptive statistics will be presented for measurements of limb circumference (for each measurement location separately), by time point of assessment (screening (V0), baseline (V1), interim (V2), and final (V3) visit), overall and by study arm.
   Descriptive statistics will be presented for change from baseline (V1) in limb circumference, separately for each measurement location, by time point of assessment (change from baseline (V1) at interim (V2) and at final (V3) visit), overall and by study arm.

   Box-plots (time on x-axis, separate plot for each study arm) will be provided to present the outcome

measure in time.

10. Sub-bandage pressure levels retention (difference of the pressure levels, measured at the time of application and before the next dressing change)
    Descriptive statistics will be presented for sub-bandage pressure levels retention (difference of the pressure levels, measured at the time of application and before the next dressing change), for all time points of assessment combined (i.e. this includes each pair of consecutive visits – starting from baseline (V1) to the next actual visit, including any additional visits, interim visit and end final/early termination visit; the repeated nature of the data will be neglected), overall and by study arm.

    Box-plots (separate plot for each study arm) will be provided to present the outcome measure in time.

7.2.5 Other collected data

1. Wound cleaning/debridement
   Descriptive statistics will be presented for data on wound cleaning/debridement application, by time point of assessment (screening (V0), baseline (V1), interim (V2), and final (V3) visit), overall and by study arm. Analysis will be performed in FAS.

2. Application of assigned product
   Data on application of assigned product (type of the dressing(s), average number of pieces per dressing change, total duration of treatment in days (V3 date – V1 date + 1 day), number of dressing changes during the treatment, frequency of dressing changes (total duration of treatment in days (V3 date – V1 date + 1 day) divided by number of dressing changes during the treatment), and total number of dressings used during the study) will be summarized using descriptive methods, overall and by study arm. Data from all visits (including additional) will be included in this analysis. Analysis will be performed in FAS.

3. Complete healing assessment
   Time to complete wound healing (first timepoint at which complete wound healing was reported, i.e. wound area = 0 or study termination due to complete wound healing) from treatment start (V1) will be summarized and analysed using survival analysis methods, overall and by study arm. Plot of Kaplan-Meier estimator of cumulative incidence curve will be provided, as well as median of time to event with 95% confidence interval and cumulative incidence at selected time points with 95% confidence interval estimated using Kaplan-Meier method will be presented. Analysis will be performed in FAS.

7.2.6 Subgroup analysis

As a part of exploratory analyses, efficacy analyses (primary endpoint and secondary efficacy endpoints) will be performed in subgroups by maceration grade (absent, minimal, moderate, or severe) at the study entry (i.e. at baseline (V1)). Methods to be used are analogical to those described for the primary analysis,

but will be applied on a subgroups by maceration grade. In case of small size of subgroups (<20 patients in the subgroup), subgroups may be combined.

7.3 SOFTWARE

Analysis will be performed using R version 4.5.0 or later version software.

8 SENSITIVITY ANALYSIS

FAS will be primary analysis population for efficacy assessment and PPS will be a population used in sensitivity analysis in efficacy assessment.

9 INTERIM ANALYSIS

Interim analysis is planned upon randomisation of 75 patients (50% of the planned study population), and will be performed while first 75 randomized patients complete the study or terminate early from the study. Interim analysis will be limited to the assessment of results based on the investigator's assessment (i.e. subjects' disposition, demographics & baseline characteristics, primary endpoint assessed on the investigator's assessment data, secondary efficacy endpoints assessed on the investigator's assessment data, secondary safety endpoints). As interim analysis will not cover assessment of primary endpoint on independent assessment of the wound photos (i.e. primary analysis of primary endpoint), no corrections for multiple testing will be applied.

10 DEVIATIONS FROM PREVIOUS VERSION OF ANALYSIS PLAN

Additional analysis should be described by a new version of SAP.

11 QUALITY CHECK PLAN

Checks will include statistical programming language R code review, checks of frequencies and descriptive statistics, checks of primary and secondary endpoints analysis, report consistency with SAP and review of summary part.

12 APPENDICES

Mock shells – to be prepared.

13 REPORT OUTLINE

1. Signature page

2. Summary of the results
3. Subject disposition, withdrawals and study completion
4. Demographics and baseline characteristics
5. Primary endpoint analysis
6. Secondary efficacy endpoints analysis
7. Safety data analysis (secondary safety endpoint)
8. Other collected data
9. Subgroup analyses for primary endpoint
10. Subgroup analyses for secondary efficacy endpoints

14 INDEX OF TABLES, FIGURES AND LISTINGS

Table number	Table title	Description
3.1	Subjects' disposition	Data on subjects' disposition will be summarized in table, following summaries will be reported: number of subjects screened (i.e. signed ICF), number of subjects qualified to the study at screening, number of subjects included in run-in period, number of subjects qualified to study after run-in period, number of subjects included in the each analysis set, number and percentage of patients who completed the study according to the protocol among FAS population, number and percentage of patients who dropped out of the study prematurely among FAS population along with a summary of the reasons premature termination of the study. Overall and by study arm. All patients enrolled.
3.2	Listing of subjects' disposition	A listing of data on the assigned product, analysis sets inclusion, dates of ICF sign, visit, and study end, study completion and reason for premature termination, randomization and informed consent responses will be prepared. All patients enrolled.
4.1.1	Demographics	Gender, age, weight, height, calculated BMI. Descriptive statistics, overall and by study arm. FAS
4.1.2	Listing of demographic data	Listing of demographic data: Gender, Age, Height, Weight, and calculated BMI value. FAS
4.2.1	Relevant comorbidities	In terms of presence of any relevant comorbidity and prevalence of relevant comorbidities by ICD-11 name. Overall and by study arm. FAS

4.2.2	Listing of relevant comorbidities	Listing of reported relevant comorbidities will be provided, including diagnosis and start and end date. FAS
4.3.1	Relevant concomitant medications and treatments	In terms of use of any relevant concomitant medications and treatments and prevalence of use of relevant concomitant medication by ATC levels 3 and 5 names. Overall and by study arm. FAS
4.3.2	Listing of relevant concomitant medications and treatments	Listing of reported relevant concomitant medications and treatment, including tradename / type of therapy, indications, dosage (dose and unit), application type, use frequency and start and end date. FAS
4.4	Wound history	Wound duration, calculated as difference in dates between wound onset and date of ICF sign/30 [months]; localization. Descriptive statistics, overall and by study arm. FAS
4.5	ABPI score	ABPI score at Screening and Baseline Visit. Descriptive statistics, overall and by study arm. FAS
4.6	Run-in-period results	Dressing used, amount of dressing used, applied pressure (Screening), summary of procedures provided during Run-in period, information about dressing changes, pressure measurements (V1 – Baseline). Descriptive statistics, overall. FAS
5.1.1	Maceration score by time point in W.H.A.T. assessment	Maceration score by time point (Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. FAS
5.1.2	Maceration score by time point in W.H.A.T. assessment	Maceration score by time point (Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. PPS
5.2.1	Change in maceration score in W.H.A.T. assessment	Shift from baseline in maceration score by time point (Interim and Final visit) Descriptive statistics, overall and by study arm. FAS
5.2.2	Change in maceration score in W.H.A.T. assessment	Shift from baseline in maceration score by time point (Interim and Final visit) Descriptive statistics, overall and by study arm. PPS
5.3.1	Maceration score by time point by the investigators' assessment	Maceration score – clinical score by time point (Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. FAS

5.3.2	Maceration score by time point by the investigators' assessment	Maceration score – clinical score by time point (Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. PPS
5.4.1	Change in maceration score by the investigators' assessment	Shift from baseline in maceration score – clinical score by time point (Interim and Final visit) Descriptive statistics, overall and by study arm. FAS
5.4.2	Change in maceration score by the investigators' assessment	Shift from baseline in maceration score – clinical score by time point (Interim and Final visit) Descriptive statistics, overall and by study arm. PPS
6.1.1.1	Wound size assessed by investigator, by time point, overall and by study arm	Descriptive statistics wound size (wound length, width, depth, and area estimated as width x length) assessed by investigator at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm FAS
6.1.1.2	Wound size assessed by investigator, by time point, overall and by study arm	Descriptive statistics wound size (wound length, width, depth, and area estimated as width x length) assessed by investigator at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm PPS
6.1.2.1	Change in wound size assessed by investigator, overall and by study arm	Change from baseline in wound size (wound length, width, depth, and area estimated as width x length) assessed by investigator between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS
6.1.2.2	Change in wound size assessed by investigator, overall and by study arm	Change from baseline in wound size (wound length, width, depth, and area estimated as width x length) assessed by investigator between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS
6.1.3.1	Wound size assessed in W.H.A.T., by time point, overall and by study arm	Descriptive statistics wound size (wound length, width, depth, and area) assessed in W.H.A.T., at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm FAS
6.1.3.2	Wound size assessed in W.H.A.T., by time point, overall and by study arm	Descriptive statistics wound size (wound length, width, depth, and area)assessed in W.H.A.T., at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm PPS
6.1.4.1	Change in wound size assessed in W.H.A.T., overall and by study arm	Change from baseline in wound size (wound length, width, depth, and area)assessed in W.H.A.T., between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS

6.1.4.2	Change in wound size assessed in W.H.A.T., overall and by study arm	Change from baseline in wound size (wound length, width, depth, and area)assessed in W.H.A.T., between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS
6.2.1.1	Wound bed tissue composition assessed by investigator, by time point, overall and by study arm	Descriptive statistics wound bed tissue composition (percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]),) assessed by investigator, at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm FAS
6.2.1.2	Wound bed tissue composition assessed by investigator, by time point, overall and by study arm	Descriptive statistics wound bed tissue composition (percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]),) assessed by investigator, at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm PPS
6.2.2.1	Change of wound bed tissue composition in the wound bed assessed by investigator, overall and by study arm	Change of wound bed tissue composition (percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic

		or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]),) assessed by investigator, between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS
6.2.2.2	Change of wound bed tissue composition in the wound bed assessed by investigator, overall and by study arm	Change of wound bed tissue composition (percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%]),) assessed by investigator, between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS
6.2.3.1	Wound bed tissue composition assessed in W.H.A.T., by time point, overall and by study arm	Descriptive statistics wound bed tissue composition (wound area covered by necrotic tissue [cm2], wound area covered by fibrinous tissue [cm2], wound area covered by granulated tissue [cm2], wound area covered by epithelialized tissue [cm2], derived parameter: wound area covered by necrotic or fibrinous tissue [cm2] (sum of wound area covered by necrotic tissue [cm2] and wound area covered by fibrinous tissue [cm2]),derived parameter: wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of wound area covered by necrotic tissue [cm2] and fibrinous tissue [cm2] and granulated tissue [cm2]), percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage

		of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%])) assessed in W.H.A.T., at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm FAS
6.2.3.2	Wound bed tissue composition assessed in W.H.A.T., by time point, overall and by study arm	Descriptive statistics wound bed tissue composition (wound area covered by necrotic tissue [cm2], wound area covered by fibrinous tissue [cm2], wound area covered by granulated tissue [cm2], wound area covered by epithelialized tissue [cm2], derived parameter: wound area covered by necrotic or fibrinous tissue [cm2] (sum of wound area covered by necrotic tissue [cm2] and wound area covered by fibrinous tissue [cm2]),derived parameter: wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of wound area covered by necrotic tissue [cm2] and fibrinous tissue [cm2] and granulated tissue [cm2]), percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%])) assessed in W.H.A.T., at all time points of assessment (Baseline, Interim and Final visit), overall and by study arm PPS
6.2.4.1	Change of wound bed tissue composition in the wound bed assessed in W.H.A.T., overall and by study arm	Change of wound bed tissue composition (wound area covered by necrotic tissue [cm2], wound area covered by fibrinous tissue [cm2], wound area covered by granulated tissue [cm2], wound area covered by epithelialized tissue [cm2], derived parameter: wound area covered by necrotic or fibrinous tissue [cm2] (sum of wound area covered by necrotic tissue [cm2] and wound area covered by fibrinous tissue [cm2]),derived parameter: wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of wound

		area covered by necrotic tissue [cm2] and fibrinous tissue [cm2] and granulated tissue [cm2]), percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%])) based on the W.H.A.T. measurements, between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS
6.2.4.2	Change of wound bed tissue composition in the wound bed assessed in W.H.A.T., overall and by study arm	Change of wound bed tissue composition (wound area covered by necrotic tissue [cm2], wound area covered by fibrinous tissue [cm2], wound area covered by granulated tissue [cm2], wound area covered by epithelialized tissue [cm2], derived parameter: wound area covered by necrotic or fibrinous tissue [cm2] (sum of wound area covered by necrotic tissue [cm2] and wound area covered by fibrinous tissue [cm2]),derived parameter: wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of wound area covered by necrotic tissue [cm2] and fibrinous tissue [cm2] and granulated tissue [cm2]), percentage of wound area covered by necrotic tissue [%], percentage of wound area covered by fibrinous tissue [%], percentage of wound area covered by granulated tissue [%], percentage of wound area covered by epithelialized tissue [%], derived parameter: percentage of wound area covered by necrotic or fibrinous tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%]), derived parameter: percentage of wound area covered by necrotic or fibrinous or granulated tissue [%] (sum of percentage of wound area covered by necrotic tissue [%] and percentage of wound area covered by fibrinous tissue [%] and percentage of wound area covered by granulated tissue [%])) assessed in W.H.A.T., between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS

6.3.1.1	Wound infection status during the study	Wound infection status during the study (CDC, TILI score) at all time points of assessment (Screening, Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. FAS
6.3.1.2	Wound infection status during the study	Wound infection status during the study (CDC, TILI score) at all time points of assessment (Screening, Baseline, Interim and Final visit) Descriptive statistics, overall and by study arm. PPS
6.3.2.1	Change of wound infection status during the study	Shift from baseline of wound infection status during the study (CDC, TILI score) between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS
6.3.2.2	Change of wound infection status during the study	Shift from baseline of wound infection status during the study (CDC, TILI score) between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS
7.1.1	Overall summary of reported adverse events	The total number of events, number and percentage of subjects who experienced any AEs, any serious AEs, any ADEs, and any serious ADEs Descriptive statistics, overall and by study arm. SAS
7.1.2.	AEs characteristics	In terms of seriousness, severity, relationship to study procedure and study product, action taken, and outcome Descriptive statistics, overall and by study arm. SAS
7.1.3	SAEs characteristics	In terms of seriousness, severity, relationship to study procedure and study product, action taken, and outcome Descriptive statistics, overall and by study arm. SAS
7.1.4	ADEs characteristics	In terms of seriousness, severity, relationship to study procedure and study product, action taken, and outcome Descriptive statistics, overall and by study arm. SAS
7.1.5	SADEs characteristics	In terms of seriousness, severity, relationship to study procedure and study product, action taken, and outcome Descriptive statistics, overall and by study arm. SAS
7.1.6	Incidence and count of AEs by Level 1 and level 2 codes	Incidence and counts of AEs will be summarized by Level 1 and level 2 codes Descriptive statistics, overall and by study arm. If a subject has more than one occurrence of the same PT, then the PT will be counted only once for that subject under the SOC for which it was experienced SAS

7.1.7	Incidence and count of SAEs by Level 1 and level 2 codes	Incidence and counts of SAEs will be summarized by Level 1 and level 2 codes Descriptive statistics, overall and by study arm. If a subject has more than one occurrence of the same PT, then the PT will be counted only once for that subject under the SOC for which it was experienced SAS
7.1.8	Incidence and count of ADEs by Level 1 and level 2 codes	Incidence and counts of ADEs will be summarized by Level 1 and level 2 codes Descriptive statistics, overall and by study arm. If a subject has more than one occurrence of the same PT, then the PT will be counted only once for that subject under the SOC for which it was experienced SAS
7.1.9	Incidence and count of SADEs by Level 1 and level 2 codes	Incidence and counts of SAEDs will be summarized by Level 1 and level 2 codes Descriptive statistics, overall and by study arm. If a subject has more than one occurrence of the same PT, then the PT will be counted only once for that subject under the SOC for which it was experienced SAS
7.1.10	Listing of AEs	All AEs will be listed in by-subject data listings SAS
7.1.11	Listing of AEs reported for subjects not included in SAS	All AEs will be listed in by-subject data listings Subjects not included in SAS
7.1.12	Overall summary of reported device deficiencies	The total number of events, number and percentage of subjects who experienced any device deficiencies Descriptive statistics, overall and by study arm. SAS
7.1.13	DDs characteristics	In terms of potential complications Descriptive statistics, overall and by study arm. SAS
7.1.14	Incidence and counts of DDs by DD description	Incidence and counts of device deficiencies will be summarized by device deficiency description. If a subject has more than one occurrence of the same device deficiency description, then the description will be counted only once for that subject. Descriptive statistics, overall and by study arm. SAS
7.1.15	Listing of DDs	All DDs will be listed in by-subject data listings SAS
7.1.16	Listing of DDs reported for subjects not included in SAS	All DDs will be listed in by-subject data listings Subjects not included in SAS
6.4.1.1	Wound exudation and presence of peri-wound oedema	Assessment of wound exudation (wound exudation status and character of wound exudation) and presence of peri-wound oedema (supported by other measures of

		surrounding skin assessment, i.e. presence of erosion, maceration, dryness/scaling, oedema, redness, moist, other) at all time points of assessment (Screening, Baseline, Interim and Final visit) FAS
6.4.1.2	Wound exudation and presence of peri-wound oedema	Assessment of wound exudation (wound exudation status and character of wound exudation) and presence of peri-wound oedema (supported by other measures of surrounding skin assessment, i.e. presence of erosion, maceration, dryness/scaling, oedema, redness, moist, other) at all time points of assessment (Screening, Baseline, Interim and Final visit) PPS
6.4.2.1	Change of wound exudation and presence of peri-wound oedema	Shift from baseline of assessment of wound exudation and presence of oedematous surrounding skin abnormality between Baseline-Interim and Baseline-Final visit, overall and by study arm, FAS
6.4.2.2	Change of wound exudation and presence of peri-wound oedema	Shift from baseline of assessment of wound exudation and presence of oedematous surrounding skin abnormality between Baseline-Interim and Baseline-Final visit, overall and by study arm, PPS
6.5.1.1	Pain measured by NRS, by time point, overall and by study arm	Wound related pain measured by NRS at all time points of assessment (Baseline, Interim, Final) Descriptive statistics, overall and by study arm FAS
6.5.1.2	Pain measured by NRS, by time point, overall and by study arm	Wound related pain measured by NRS at all time points of assessment (Baseline, Interim, Final) Descriptive statistics, overall and by study arm PPS
6.5.2.1	Change from baseline in pain measured by NRS, by time point, overall and by study arm	Change from baseline in wound related pain measured by NRS at Interim and at Final visit, overall and by study arm FAS
6.5.2.2	Change from baseline in pain measured by NRS, by time point, overall and by study arm	Change from baseline in wound related pain measured by NRS at Interim and at Final visit, overall and by study arm PPS
6.6.1.1	Product usability, assessed by user for both Suprasorb®X+PHMB (Pro) and Rosidal 1C, overall and by study arm	Based on external data. Descriptive statistics, overall and by study arm FAS
6.6.1.2	Product usability, assessed by user for both Suprasorb®X+PHMB (Pro) and	Based on external data. Descriptive statistics, overall and by study arm PPS

	Rosidal 1C, overall and by study arm	
6.6.2.1	Product usability, assessed by patient for both Suprasorb®X+PHMB (Pro) and Rosidal 1C, overall and by study arm	Patient's questionnaire about the product, Descriptive statistics, overall and by study arm FAS
6.6.2.2	Product usability, assessed by patient for both Suprasorb®X+PHMB (Pro) and Rosidal 1C, overall and by study arm	Patient's questionnaire about the product, Descriptive statistics, overall and by study arm PPS
6.7.1.1	Patient's quality of life (assessed by means of Wound QoL-17 scale), overall and by study arm	Wound QoL-17 (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday", as well as responses for each item), at all time points of assessment (Screening, Baseline, Interim, Final) Descriptive statistics, overall and by study arm FAS
6.7.1.2	Patient's quality of life (assessed by means of Wound QoL-17 scale), overall and by study arm	Wound QoL-17 (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday", as well as responses for each item), at all time points of assessment (Screening, Baseline, Interim, Final) Descriptive statistics, overall and by study arm PPS
6.7.2.1	Change in patient's quality of life (assessed by means of Wound QoL-17 scale), overall and by study arm	Change from baseline in patient's quality of life assessed by means of Wound QoL-17 scale (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday"), at Interim and at Final visit, overall and by study arm, Descriptive statistics, overall and by study arm FAS
6.7.2.2	Change in patient's quality of life (assessed by means of Wound QoL-17 scale), overall and by study arm	Change from baseline in patient's quality of life assessed by means of Wound QoL-17 scale (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday"), at Interim and at Final visit, overall and by study arm, Descriptive statistics, overall and by study arm PPS
6.7.2.3	Change in patient's quality of life (assessed by means of Wound QoL-17 scale), run-in period	Change from screening (V0) to baseline (V1) in patient's quality of life assessed by means of Wound QoL-17 scale (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday"). Descriptive statistics, overall FAS, patients who completed run-in period
6.7.2.4	Change in patient's quality of life (assessed by means of Wound QoL-17 scale), run-in period	Change from screening (V0) to baseline (V1) in patient's quality of life assessed by means of Wound QoL-17 scale (Wound QoL-17 scale global score, subscale "Body", "Psyche", and "Everyday"),

		Descriptive statistics, overall. PPS, patients who completed run-in period
6.8.1.1	Oedema reduction, overall and by study arm	Limb circumference measurement, by location, at all time points of assessment (screening, baseline, interim, and final visit). Descriptive statistics, overall and by study arm FAS
6.8.1.2	Oedema reduction, overall and by study arm	Limb circumference measurement, by location, at all time points of assessment (screening, baseline, interim, and final visit). Descriptive statistics, overall and by study arm PPS
6.8.2.1	Change in oedema reduction, overall and by study arm	Change from baseline in Limb circumference measurement, by location, overall and by study arm, Descriptive statistics, overall and by study arm FAS
6.8.2.2	Change in oedema reduction, overall and by study arm	Change from baseline in Limb circumference measurement, by location, overall and by study arm, Descriptive statistics, overall and by study arm PPS
6.9.1	Sub-bandage pressure levels retention, overall and by study arm	Sub-bandage pressure levels retention (difference of the pressure levels, measured at the time of application and before the next dressing change), for all time points of assessment combined (i.e. this includes each pair of consecutive visits – starting from baseline (V1) to the next actual visit, including any additional visits, interim visit and end final/early termination visit; the repeated nature of the data will be neglected). Descriptive statistics, overall and by study arm FAS
6.9.2	Sub-bandage pressure levels retention, overall and by study arm	Sub-bandage pressure levels retention (difference of the pressure levels, measured at the time of application and before the next dressing change), for all time points of assessment combined (i.e. this includes each pair of consecutive visits – starting from baseline (V1) to the next actual visit, including any additional visits, interim visit and end final/early termination visit; the repeated nature of the data will be neglected) Descriptive statistics, overall and by study arm PPS
8.1	Wound cleaning/debridement	Data on wound cleaning/debridement application, by time point of assessment (screening (V0), baseline (V1), interim (V2), and final (V3) visit). Descriptive statistics, overall and by study arm. FAS

8.2	Application of assigned product	Data on application of assigned product (type of the dressing(s), average number of pieces per dressing change, total duration of treatment in days (V3 date – V1 date + 1 day), number of dressing changes during the treatment, frequency of dressing changes (total duration of treatment in days (V3 date – V1 date + 1 day) divided by number of dressing changes during the treatment), and total number of dressings used during the study). Data from all visits (including additional) will be included in this analysis. Descriptive statistics, overall and by study arm. FAS
8.3.1	Complete healing assessment	Number and percentage of patients in whom wound completely healed (wound area = 0) until the visit, at interim and final visit. Descriptive statistics, by time point of assessment (interim and final visit), overall and by study arm. FAS
8.3.2	Time to complete wound healing	Time to complete wound healing (wound area = 0) (first timepoint at which complete wound healing was reported) from treatment start (V1). Plot of Kaplan-Meier estimator of cumulative incidence curve. Median of time to event with 95% confidence interval and cumulative incidence at selected time points with 95% confidence interval estimated using Kaplan-Meier method. Overall and by study arm. FAS
9.X	Subgroup analyses for primary endpoint	
10.X	Subgroup analyses for secondary efficacy endpoints	

15 SIGNATURES

	Name	Date / Signature
CleanDataLabs prepared by:	Teresa Szenk *Statistician*	*e-Signature*
CleanDataLabs checked and accepted by:	Agnieszka Segiet-Święcicka *Senior Statistician*	*e-Signature*
Sponsor's Representative accepted by:	*Martin Abel*	*e-Signature*
Sponsor's Representative Accepted by:	*Daria Trofimenko*	*e-Signature*
CRO's Representative Accepted by:	Patrycja Buczak-Kula *Clinical Operations Director*	*e-Signature*