Confidential

Statistical Analysis Plan

For the Clinical Trial of Protocol BTF16-AP-401

A pilot study to evaluate efficacy and safety of hydrophilic polyurethane foam dressing in patients with pressure ulcer

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Abbreviation

ADE	: Adverse Device Effect
AE	: Adverse Event
ALP	: ALkaline Phosphatase
ATC	: Anatomical Therapeutic Chemical
BS	: Biostatistician
BSM	: Biostatistician Manager
CRM	: Clinical Research Manager
CS	Clinically Significant
CSSC	: Clinical Signs and Symptoms Checklist
FAS	: Full Analysis Set
LOCF	: Last Observation Carried Forward
MedDRA	: Medical Dictionary for Regulatory Activities
NPUAP	: National Pressure Ulcer Advisory Panel
PUSH	: Pressure Ulcer Scores for Healing
SADE	: Serious Adverse Device Effect
SAE	: Serious Adverse Effect
WBC	: White Blood Cell

1. Objective

The Statistical Analysis Plan is a guideline for Protocol No.BTF16-AP-401 to minimize the bias and maximize the precision so that the final results, conclusion, application and the entire details regarding proposed analysis of the clinical trial can be reliably evaluated.

2. Purpose of Study

The aim of this study is to exploratively assess the efficacy and safety of hydrophilic polyurethane foam in pressure ulcer patients.

For this purpose, the percentage of completely healed patients and the time to complete healing will be assessed after applying a study device, Medifoam® or Betafoam®, for 12 weeks to pressure ulcer patients. In addition, the pressure ulcer size reduction rate over 12 weeks will be evaluated.

3. Study Design

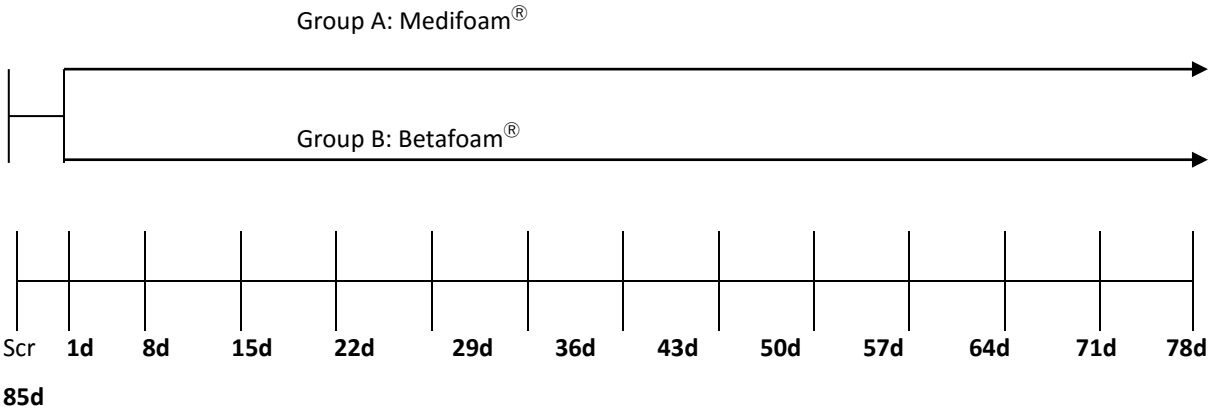
This is a single-center, randomized, 2-arms, open-label pilot study.

Subjects who consent to the study will be assessed for eligibility with screening tests. Subjects can have a 2-week screening period.

After screening, subjects who meet the inclusion/exclusion criteria will apply Medifoam® or Betafoam® for 12 weeks, after randomization. Targeted subjects are outpatient clinic or hospitalized patients. Subjects will make once weekly site visits.

During the treatment period, dressing is performed twice weekly, but additional dressing changes are allowed, depending on the condition of the pressure ulcer, such as excessive exudates at the study ulcer. Nevertheless, the frequency of additional dressing is limited to twice daily. On the weekly site visit days, the investigator(or clinical research coordinator) will change the dressing; on other occasions, the subject or guardian will perform self-dressing. Subjects who achieve complete healing of the target pressure ulcer within 12 weeks will have early completion.

Efficacy assessment is conducted for a total of 12 times at a 1-week interval, after the investigational device application (8d, 15d, 22d, 29d, 36d, 43d, 50d, 57d, 64d, 71d, 78d, 85d). At each efficacy assessment, the investigator (or clinical research coordinator) should take a digital photograph of the target pressure ulcer and retain it as a source document.



4. Inclusion/Exclusion Criteria

Inclusion

1) Adults aged at least 19 years old as of the consent date
2) Pressure ulcer of the NPUAP(National Pressure Ulcer Advisory Panel) Stage III at screening
3) Pressure ulcer size of 3-100 cm^2 at screening
4) Written consent provided by the subject or representative
   (In case a subject has more than one pressure ulcers that meet all inclusion criteria, the largest one is selected as a target lesion.)

Exclusion

1) Any study ulcer of the NPUAP Stage I, II or IV
2) Diabetic ulcer or Venous ulcer (or stasis ulcer)
3) Past history of surgical treatment within 1 year or irradiation at the target pressure ulcer within 1 year
4) Hypersensitivity reaction to this product or povidone-iodine
5) Hyperthyroidism or thyroid disorder requiring drug treatment
6) Signs of a current underlying systemic infection (sepsis/bacterial infection/tuberculosis) or cellulitis or osteomyelitis
7) Type 1 diabetes

8) Current malnutrition
9) Heavy smoker: Current smoking level of ≥1 pack (20 cigarettes)/day of tobacco
10) Drug or alcohol addiction
11) Requirement of immunosuppressants during the study or current chemotherapy or radiotherapy
12) Application of other investigational product/medical device within 1 month prior to the investigational device application (1d)
13) Pregnant or breastfeeding women
14) Other renal, hepatic, neurological, immunological disorder that may interfere with the wound healing process, at the discretion of the investigator

5. Discontinuation/Withdrawal and early completion criteria

Discontinuation and withdrawal criteria

In case of meeting the following criteria for study device discontinuation, application of the study device and the study should be discontinued, and the reason for discontinuation and findings should be recorded in the Case Report Form.

- Criteria for discontinuation of the study device application

1) Acute reactions (allergy, hypersensitivity reactions, etc.) to the study device
2) It is determined that continuation of the study is difficult due to an accidental intercurrent condition.
3) It is determined that continuation of the study is impossible due to worsening of the pressure ulcer (Stage 4 or higher).
4) Debridement was performed during the study, after the study device application.
5) Pregnant during the study period
6) It is otherwise determined by the investigator that continued application of the study device is not appropriate due to reasons such as serious malnutrition, etc.
7) It is determined by the investigator that study participation is not appropriate due to a “serious adverse event”.

“Serious adverse event” is an event, irrespective of a causal relationship with the study device, that is as follows:

① Results in death or is life-threatening

② Requires inpatient hospitalization or prolongation of existing hospitalization

③ Results in persistent or significant disability or dysfunction

④ Results in congenital anomaly or birth defect

⑤ Other medically important event as identified by the Investigator

In case of discontinuation due to worsening of a pressure ulcer, the treating physician will ensure safety of the patient with appropriate tests and treatment, equivalent to the case of an adverse event.

Early completion criteria

Subjects who achieve complete healing* of the target pressure ulcer will complete the study early. Subjects who can complete the study early will undergo all tests scheduled for the End-of-Study (85d) visit and then complete the study.

(* Complete healing: Defined as the condition with the epithelial tissue covering 100% of the study ulcer, no abrasion or ulceration, intact dermis and epidermis.)

6. Statistical Analysis Population

Data obtained from subjects in this study will be analyzed as the SS(Safety Set) and the FAS(Full Analysis set).

1) In the SS(Safety set), data obtained from subjects who were enrolled in the study, had at least 1 application of the study device, and had at least 1 safety assessment will be analyzed.
2) In the FAS(Full analysis set), data obtained from subjects who were enrolled in the study, had at least 1 application of the study device and then had at least 1 available endpoint of main interest review will be included in analysis.

7. Analysis of endpoints

7.1 Efficacy Endpoints

(1) Endpoints of main interest

① Number of patients with complete healing# of ulcer within 12 weeks

: Subjects who achieved complete healing and had early completion or completion at the end of 12

weeks will be included.

② Time to complete healing# of ulcer within 12 weeks

: Time to complete healing is calculated as the number of days from baseline (1d).

(# The definition of complete healing: Epithelial tissue covering 100% of the study ulcer, no abrasion or ulceration, intact dermis and epidermis)

③ Pressure ulcer size by each time point

④ Pressure ulcer size reduction rate based on a scale at each time point

Reduction Rate=

$$\frac{\text{Pressure ulcer size on 1d* – Pressure ulcer size at each time point from 8d to End-of-Study**}}{\text{Pressure ulcer size on 1d}} \text{ X 100\%}$$

* Using a scale-based pressure ulcer area (cm^2) measured prior to the study device application

** Using a scale-based pressure ulcer area (cm^2) without re-epithelization*** measured at each time point after the study device application

(***Re-epithelization: New epithelial tissue covering the pressure ulcer, with no exudate, transudate, or avascular tissue)

(2) Other endpoints

① PUSH reduction rate at each time point

$$\text{Reduction rate} = \frac{\text{PUSH score on 1d – PUSH score at each time point}}{\text{PUSH score on 1d}} \text{ X 100\%}$$

② Dressing change frequency during the entire study period

: Calculated as the additional dressing frequency beyond twice daily

③ Number of subjects with early completion due to complete healing during the study

④ Incidence of new infections at the pressure ulcer until Week 12 based on the CSSC

$$\text{Infection incidence} = \frac{\text{Number of subjects with at least 1 new infection** until Week 12, after the study device application}}{\text{Total number of subjects}} \text{ X 100\%}$$

(** Infection: Presence of 'Purulent exudates' or 2 or more symptoms of the CSSC. However, for subjects with an infection at baseline, it is defined as development of an additional symptom other than those confirmed at baseline or recurrence of baseline-identified symptoms after being completely healed.)

7.2 Safety Endpoints

The followings will be evaluated for safety assessment.

1) Adverse event

At every visit, review both local adverse events at the target pressure ulcer and other adverse events.

(Local adverse events at the target pressure ulcer: Erythema, edema, itching, flare, rash, others)

2) Vital signs

Vital signs are analyzed by measuring at every visit until study completion. Measured vital signs are blood pressure(), pulse, and body temperature. In addition, body weight is measured at screening, Week 4 and at the End-of-Study visit. Visits conducted outside of the site will not include body weight measurement.

3) Laboratory tests and physical examination

Laboratory tests are conducted at screening and study completion. For physical examination, normal/abnormal status of findings at screening is confirmed, and it is assessed whether the subject is eligible for study participation. Physical examination is also performed at every subsequent visit. Visits conducted outside of the site will not include physical examination.

8. Statistical Methodology by Endpoints

Analysis of Efficacy Endpoints

(1) Analysis of endpoints of main interest

① For subjects achieving complete healing within 12 weeks, present frequency and percentage. Fisher's exact test will be performed to compare Medifoam and Betafoam treatment groups.

② For the time to 100% complete healing, analyze using the Kaplan-Meier method. Time table for subjects to 100% complete healing will be presented and the survival Plot will be shown as a figure. Subjects not achieving 100% complete healing within 12 weeks will not be considered for evaluation for end point of main interest though ulcer size reduction will be evaluated for those subjects.

③ For the pressure ulcer size by each time point, present the mean, median, min, max and standard deviation. t-test will be conducted to compare Medifoam and Betafoam, and paired t-test will be used to see the difference between each post visit and baseline(1d).

④ For the pressure ulcer size reduction rate, present the mean, median, min, max and standard deviation. t-test will be conducted to compare Medifoam and Betafoam.

⑤ For the analysis for efficacy, conduct sub-analyses by use of topicalantibiotics and glucocorticoids for the pressure ulcer during the study. t-test will be performed to compare Medifoam and Betafoam, and paired t-test will be used to see the difference between post visits and baseline(1d).

(2) Analysis of other endpoints

For other endpoints, present the mean, median, min, max and standard deviation for the continuous variable PUSH reduction rate at each time point, and frequency and percentage for categorical variables of Dressing change frequency, Number of subjects with early completion due to complete healing, and Incidence of new infections at the pressure ulcer after investigational device application. t-test and paired t-test will be conducted for PUSH reduction rate while Fisher's exact test will be used to see the difference between Meidfoam and Betafoam for Dressing change frequency, Number of subjects with early completion , and Incidence of new infections .

Analysis of safety endpoints

(1) Adverse events

List all adverse events that occurred by group. Record the frequency of adverse events related or unrelated with the investigational device by group. For the number of adverse events and the percentage of subjects who had at least 1 adverse event, present the 95% confidence interval in each treatment group. Analyze adverse events separately for local adverse events at the target pressure ulcer and other adverse events.

(2) Laboratory test findings

For continuous data, present descriptive statistics (mean, standard deviation, median, minimum, maximum) by group and time point. In addition, tabulate the proportion of normal/abnormal results by time point in each group.

(3) Vital signs

For continuous variables, present descriptive statistics (mean, standard deviation, median, minimum, maximum) for the baseline and end-of-study test findings by group and visit time point.

9. Handling Missing Values

For subjects with a missing value during the study or who are withdrawn from the study prior to study completion, efficacy analysis will be conducted by applying the LOCF(Last observation Carried Forward), only in case such subjects have available endpoints of main interest assessment results after the investigational device application. However, in case of missing values for other endpoints and safety endpoints, raw data will be used for analysis, without applying LOCF.

10. Midterm Analysis

The midterm analysis will not be conducted for this study.

11. Others

Further Consideration

- In principle, the analysis shall follow the methods presented in Protocol No. BTF16-AP-401 and the general items regarding statistical analysis procedure shall be described.
- For continuous variables, Shapiro-Wilk test with p-value 0.05 will be used for normality test. t-distribution approximation method will be used for Wilcoxon rank sum test.
- Chi-square test will used on half of Fisher's exact test in case when SAS 9.3 cannot handle the amount of test calculation.

12. Dummy Table List

Analysis Criteria/ Analysis Set	Table No.	Analysis Variables	Group Variables	Note
Disposition of Subjects	0101	Disposition of Subjects	ALL	
	0102	Detailed reports on discontinued subjects	ALL	
	0103	Analysis Set	ALL	
Demographics FAS	0201	Gender	V1(Screening)	Medifoam vs. Betafoam
	0201	Age(Years)	V1(Screening)	Medifoam vs. Betafoam
	0201	Age(20-29, 30-39, 40-49, 50-59, 60-69, 70 or more)	V1(Screening)	Medifoam vs. Betafoam
	0201	Body Weight	V1(Screening)	Medifoam vs. Betafoam
	0201	Height	V1(Screening)	Medifoam vs. Betafoam
	0201	Breast Feeding(Female Only)	V1(Screening)	Medifoam vs. Betafoam
	0201	Possibility of Pregnancy(Female Only)	V1(Screening)	Medifoam vs. Betafoam
	0201	Reason for not being able to pregnant	V1(Screening)	
	0201	Countermeasure for pregnancy	V1(Screening)	
	0201	Alcohol consumption	V1(Screening)	Medifoam vs. Betafoam
	0201	Nicotine consumption	V1(Screening)	Medifoam vs. Betafoam
	0201	Urine HCG test results	V1(Screening)	Medifoam vs. Betafoam
Medical History FAS	0301	Pressure Ulcer	V1(Screening)	Medifoam vs. Betafoam
	0302	Hypersensitivity	V1(Screening)	Medifoam vs. Betafoam
	0303	Other Medical History(Past/Current)	V1(Screening)	Medifoam vs. Betafoam
	0304	Past Medical History (SOC/PT)	V1(Screening)	Medifoam vs. Betafoam
	0305	Current Medical History (SOC/PT)	V1(Screening)	Medifoam vs. Betafoam
	0306	Surgical Procedure	V1(Screening)	Medifoam vs. Betafoam
	0307	List of Surgical Procedure and Indications for subjects who had surgical procedure	V1(Screening)	Medifoam vs. Betafoam
Medication History FAS	0401	Prior/Concomitant Medication(Y/N)	ALL	Medifoam vs. Betafoam
	0402	Prior Medication in detail ((Level 1 / Level 3) of WHO ATC)	ALL	Medifoam vs. Betafoam

Analysis Criteria/ Analysis Set	Table No.	Analysis Variables	Group Variables	Note
	0403	Concomitant Medication in detail ((Level 1 / Level 3) of WHO ATC)	ALL	Medifoam vs. Betafoam
Pressure ulcer assessment at Screening(Visit1) FAS	0501	List of Body Parts where Pressure Ulcer occurred	V1(Screening)	Medifoam vs. Betafoam
	0502	Pressure ulcer size at Screening	V1(Screening)	Medifoam vs. Betafoam
Analysis of endpoints of main interest FAS	0601	Number of patients with complete healing of ulcer within 12 weeks	ALL	Medifoam vs. Betafoam
	0602	Time taken for subjects to reach complete healing of ulcer within 12 weeks	ALL	Medifoam vs. Betafoam
	Figure 0601	Time to complete healing of ulcer within 12 weeks	ALL	Medifoam vs. Betafoam, Kaplan-Meire Plot
	0603	Pressure ulcer size by each time point and change from 1d (Baseline)	ALL	Medifoam vs. Betafoam
	0604	Pressure ulcer size reduction rate based on scale at each time point	ALL	Medifoam vs. Betafoam
	0605	Sub-analysis on Pressure ulcer size reduction rate based on scale at each time point by use of topical antibiotics	ALL	Medifoam vs. Betafoam,
	0606	Sub-analysis on Pressure ulcer size reduction rate based on scale at each time point by use of glucocorticoids	ALL	Medifoam vs. Betafoam
Analysis of other endpoints FAS	0701	PUSH reduction rate at each time point	ALL	Medifoam vs. Betafoam
	0702	Dressing change frequency during the entire study period for subjects on Medifoam	ALL	Medifoam vs. Betafoam
	0703	Dressing change frequency during the entire study period for subjects on Betafoam	ALL	Medifoam vs. Betafoam
	0704	Number of subjects with early completion due to complete healing during the study	ALL	Medifoam vs. Betafoam
	0705	Number of subjects by CSSC signs and symptoms per each visit for subjects on Medifoam	ALL	Medifoam vs. Betafoam
	0706	Number of subjects by CSSC signs and symptoms at each visit for subjects on Betafoam	ALL	Medifoam vs. Betafoam
	0707	Incidence of new infections at the pressure ulcer until Week 12 based on the CSSC	ALL	
Physical Examination Safety	0801~0813	Normal(or Abnormal(NCS)/Abnormal(CS)) cross table for Physical Examination	ALL	Medifoam vs. Betafoam McNemar Test
Vital Sign Safety	0901	Vital Sign Results and Change from Baseline(Temperature)	ALL	Medifoam vs. Betafoam
	0902	Vital Sign Results and Change from Baseline(SBP, DBP, Pulse)	ALL	Medifoam vs. Betafoam
Laboratory Test Safety	1001	Laboratory Test results and Change from Baseline (Hematology)	ALL	Medifoam vs. Betafoam
	1002	Normal(or Abnormal(NCS)/Abnormal(CS)) cross table for Laboratory Test (Hematology)	ALL	Medifoam vs. Betafoam McNemar Test
	1003	Laboratory Test results and Change from Baseline (Blood Chemistry)	ALL	Medifoam vs. Betafoam

Analysis Criteria/ Analysis Set	Table No.	Analysis Variables	Group Variables	Note
	1004	Normal(or Abnormal(NCS)/Abnormal(CS)) cross table for Laboratory Test (Blood Chemistry)	ALL	Medifoam vs. Betafoam McNemar Test
Adverse Events Safety	1101	AE Summary(AE, ADE, SAE, SADE)	ALL	Medifoam vs. Betafoam
	1102~1105	Number and Percentage of subjects with (AE, ADE, SAE, SADE)	ALL	Medifoam vs. Betafoam
	1106~1111	Incidence rate, Number and frequency of (Local AE, ADE, SAE, SADE) by Severity, SAE, Outcome, Relationship with the clinical device, Action taken with the Device, Seriousness	ALL	Medifoam vs. Betafoam
	1112~1117	Incidence rate, Number and frequency of (Other AE, ADE, SAE, SADE) by Severity, SAE, Outcome, Relationship with the clinical device, Action taken with the Device, Seriousness	ALL	Medifoam vs. Betafoam

13. TLFs

1) Disposition of Subjects

Table 0101 Disposition of Subjects who participated in the study

	Medifoam	Betafoam	Total
Subjects who signed the Informed Consent form	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Screening	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Screening Failure	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Screening Failure1	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Screening Failure2	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Screening Failure3	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Randomized	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Discontinuation 1	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Discontinuation 2	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason for Discontinuation 3	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Subjects who completed the trial (including Early completion)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)

Table 0102 Detailed reports on discontinued subjects

Treatment Group	Screening No.	Randomization No.	Informed Consent Date	Discontinuation Date	Reason for Discontinuation

Table 0103 Analysis Set

	Medifoam	Betafoam	Total
Randomized	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason1 for Safety excluded	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason2 for Safety excluded			
Safety Set	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason1 for FAS excluded	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reason2 for FAS excluded	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
FAS	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)

2) Demographics

Analysis Set: FAS

Table 0201 Demographics

		Medifoam	Betafoam	Total	p-value
Gender	Male	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	Female	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Age (Years)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Age (Categorical)	19~29	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	30~39	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	40~49	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	50~59	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	60~69	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	70<	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Body Weight (kg)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Height (cm)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Breast Feeding (Female Only)	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Possibility of Pregnancy (Yes/No)	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Reason for not being able to get pregnant	Menopause 1 year ago	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Hysterectomy/bilateral ovariectomy surgery	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Countermeasure for pregnancy	Yes (Condom)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Yes (Oral contraception)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Yes (Injectable contraceptive)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

	Yes (Insertable contraceptive)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Yes (Intrauterine contraceptive device)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Alcohol consumption	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Alcohol consumption (If yes, alcohol per week)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Nicotine consumption	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Nicotine consumption(If yes, cigarettes per day)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Urine HCG Test	Done	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	Not Done	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Not Applicable	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Urine Test Results	Negative	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	Positive	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

Note) Percentage is based on FAS Set subjects within each column.

Note) *: t-test, ¥: Wilcoxon rank sum test, ‡: Fisher's exact test

3) Medical History

Analysis Set: FAS

Table 0301 Pressure Ulcer

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Prior surgical history of target ulcer within 1 year	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Prior irradiation history of the target ulcer within 1 year	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Malnutrition Status	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Mobility and condition	Ambulatory	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	Stays sitting only	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Stays lying only	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Stays lying and sitting only	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Duration since occurrence of pressure ulcer(weeks)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	

‡: Fisher's exact test *: t-test, ¥: Wilcoxon rank sum test

Table 0302 Hypersensitivity

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Hypersensitive to povidone-iodine or similar medical devices in the past	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

‡: Fisher's exact test

Table 0303 Other medical history and concomitant illness

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Past Medical History	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Current Medical History	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

‡: Fisher's exact test

Table 0304 Past Medical history (SOC/PT*)

		Medifoam (N=xx)			Betafoam (N=xx)			Total (N=xx)		
		n	(%)	freq	n	(%)	freq	N	(%)	freq
Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx
SOC	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx
	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx

Note) SOC: System Organ Class, PT: Preferred Term, * Coded in *MedDRA Ver 18.1 or latest version*

Table 0305 Current Medical history (SOC/PT*)

		Medifoam (N=xx)			Betafoam (N=xx)			Total (N=xx)		
		n	(%)	freq	n	(%)	freq	N	(%)	freq
Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx
SOC	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx
	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	Xx	(xx.xx)	xx

Note) SOC: System Organ Class, PT: Preferred Term, * Coded in *MedDRA Ver 18.1 or latest version*

Table 0306 Surgical Procedure (Yes/No)

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Surgical Procedure	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

‡: Fisher's exact test

Table 0307 List of Surgical Procedure and Indications for subjects who had surgical procedure (Indication/Surgical Procedure)

		Medifoam (N=xx)			Betafoam (N=xx)			Total (N=xx)		
		n	(%)	freq	n	(%)	freq	n	(%)	freq
Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
Indication	Surgical Procedure	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
	Surgical Procedure	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx

4) Medication History

Analysis Set: FAS

Table 0401 Prior/Concomitant Medication

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Prior Medication	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
Concomitant Medication	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

‡: Fisher's exact test

Table 0402 Prior Medication in detail((Level1/Level3) of WHO ATC*)

		Medifoam		Betafoam		Total	
		n	(%)	n	(%)	n	(%)
Total		xx	(xx.xx)	xx	(xx.xx)	xx	(xx.xx)
Level1	Level3	xx	(xx.xx)	xx	(xx.xx)	xx	(xx.xx)
	Level3	xx	(xx.xx)	xx	(xx.xx)	xx	(xx.xx)

Note) * Coded in WHO ATC Class

Table 0403 Concomitant Medication in detail ((Level 1/ Level 3) of WHO ATC*)

		Medifoam			Betafoam			Total		
		n	(%)	freq	n	(%)	freq	N	(%)	freq
Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
Level1	Level3	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
	Level3	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx

Note) Percentage is based on FAS Set subjects within each column.

Note) * Coded in WHO ATC Class

5) Pressure ulcer assessment at Screening(Visit1)

Table 0501 List of body parts where pressure ulcer occurred

	Medifoam	Betafoam	Total
Body Part	n	n	n
Location1	xx	xx	xx
Location2	xx	xx	xx
Location3	xx	xx	xx
Location4	xx	xx	xx
…	xx	xx	xx
Total	xx	xx	xx

Table 0502 Pressure ulcer size at Screening

Measurement		Medifoam	Betafoam	Total	P-value
Length(cm)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Width(cm)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	

6) Analysis of endpoints of main interest

Analysis Set: FAS

Table 0601 Number of patients with complete healing of ulcer within 12 weeks

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Complete healing of ulcer within 12 weeks	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

‡: Fisher's exact test

Table 0602Time taken for subjects to reach complete healing of ulcer within 12 weeks(in days)

		Medifoam	Betafoam	Total	P-value
Time(days)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	

Note) *: t-test, ¥: Wilcoxon rank sum test

Figure 0601 Time to complete healing of ulcer within 12 weeks

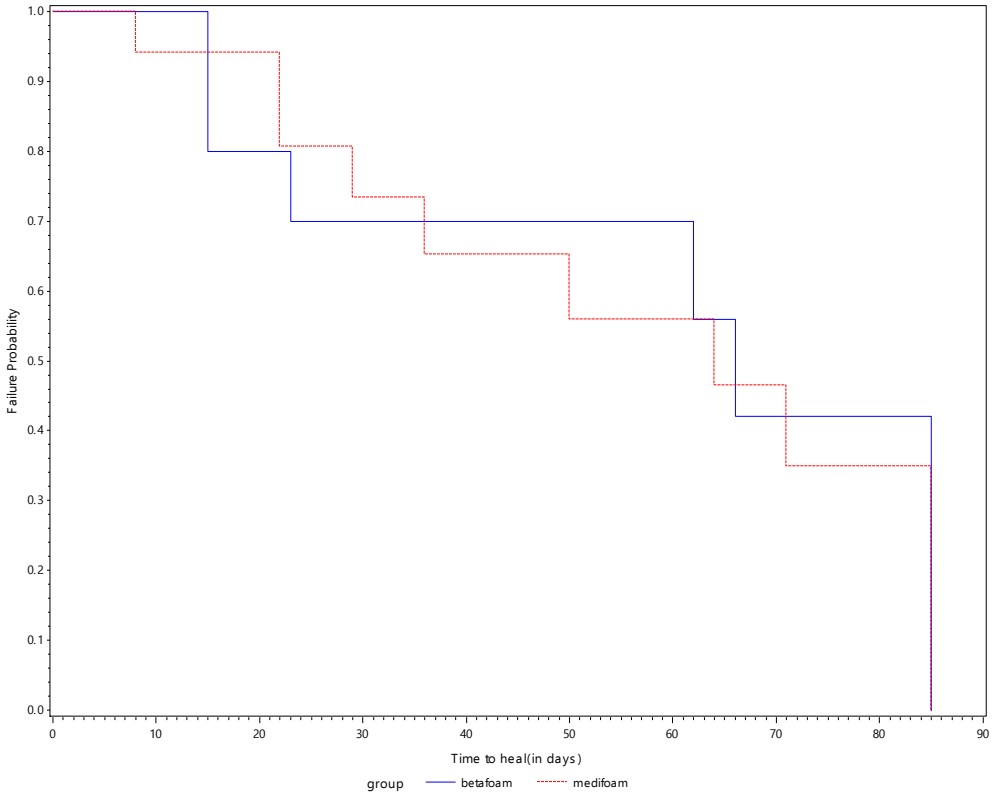


Table 0603 Pressure ulcer size by each time point and change from 1d (baseline)

Time points		Medifoam	Betafoam	Total	P-value
Visit2(1d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Visit4~Visit14	..(Middle Part omitted)..				

Note) *: t-test, ￥: Wilcoxon rank sum test

Table 0604 Pressure ulcer size reduction rate based on scale at each time point

Time points		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	P-value(within)	0.xxxx#			

Visit4~Visit13	..(Middle Part omitted)..				
Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	P-value(within)	0.xxxx#			

Note) *: t-test, ￥: Wilcoxon rank sum test #: Paired t-test, $: Wilcoxon signed rank test

Table 0605 Sub-analysis on Pressure ulcer size reduction rate based on scale at each time point by Use of topical antibiotics

Use of Topical antibiotics	Time points		Medifoam	Betafoam	Total	P-value
Topical antibiotics used	Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit4~Visit13	..(Middle Part Omitted)..				
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Topical antibiotics Not used	Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit4~Visit13	..(Middle Part Omitted)..				
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	

Note) *: t-test, ￥: Wilcoxon rank sum test

Table 0606 Sub-analysis on Pressure ulcer size reduction rate based on scale at each time point by Use of glucocorticoids

Use of glucocorticoids	Time points		Medifoam	Betafoam	Total	P-value
Glucocorticoids used	Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit4~Visit13		..(Middle Part Omitted)..			
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Glucocorticoids Not used	Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit4~Visit13		..(Middle Part Omitted)..			
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	

Note) *: t-test, ￥: Wilcoxon rank sum test

7) Analysis of Other endpoints

Analysis Set: FAS

Table 0701 PUSH reduction rate at each time point compared to baseline

Time points		Medifoam	Betafoam	Total	P-value
Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	P-value(within)	0.xxxx			
Visit4~Visit13	..(Middle Part Omitted)..				
Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	P-value(within)	0.xxxx			

Note) *: t-test, ￥: Wilcoxon rank sum test

Table 0702 Dressing change frequency per week during the entire study period for subjects on Medifoam

	Medifoam			
	Visits			
Number of Dressing Change per week	Visit3	Visit4	….	Visit14
None	N	N	N	N
One time	N	N	N	N
Two times	N	N	N	N
Three times	N	N	N	N
Four or more times	N	N	N	N
Total	N	N	N	N

Table 0703 Dressing change frequency per week during the entire study period for subjects on Betafoam

*Same as 0702

Table 0704 Number of subjects with early completion due to complete healing during the study

		Medifoam	Betafoam	Total	P-value
		n(%)	n(%)	n(%)	
Early completion due to complete healing	Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	0.xxxx‡
	No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	
	Total	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	

Note) ‡: Fisher's exact test

Table 0705 Number of subjects with CSSC signs and symptoms at each visit for subjects on Medifoam

	Medifoam			
CSSC signs and symptoms	Visit2	Visit3	….	Visit14
Increasing pain in the ulcer area	N	N	N	N
• Can't detect pain in ulcer area	N	N	N	N
• Have less pain now than in the past	N	N	N	N
• Intensity of pain remained the same	N	N	N	N
• More ulcer pain now than in the past	N	N	N	N
Erythema	N	N	N	N
Edema	N	N	N	N
Heat	N	N	N	N
Purulent exudates	N	N	N	N
Sanguinous exudates	N	N	N	N
Serous exudates	N	N	N	N
Delayed healing of the ulcer	N	N	N	N
Discoloration of granulation tissue	N	N	N	N
Friable granulation tissue	N	N	N	N
Pocketing at base of wound	N	N	N	N
Foul odor	N	N	N	N
Wound breakdown	N	N	N	N
Total	N	N	N	N

Table 0706 Number of subjects with CSSC signs and symptoms at each visit for subjects on Betafoam

*Same as Table 0705

Table 0707 Incidence of new infections at the pressure ulcer until Week 12 based on the CSSC

Treatment group	n (Incidence rate)	95% C.I. of Incidence rate	Frequency	Total

Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx
Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx

8) Physical Examination

Analysis Set: Safety

Table 0801 Normal or Abnormal (NCS)/Abnormal(CS)) cross table for Physical Examination (Visit 1 vs. Visit 2)

Visit1(Screening)		Visit2(1d)											
		Medifoam						Betafoam					
		Normal		Abnormal		Total		Normal		Abnormal		Total	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Variables	Normal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Abnormal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Total	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	(xx.xx)
P-value		0.xxxx						0.xxxx					
..Rest Variables are omitted in TLF..													

Note) Normal includes normal and NCS, while abnormal refers to CS.

Note) p-value: McNemar test

Table 0702 Normal (or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 3)

*Same as Table 0801

Table 0803 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 4)

*Same as Table 0801

Table 0804 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 5)

*Same as Table 0801

Table 0805 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 6)

*Same as Table 0801

Table 0806 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 7)

*Same as Table 0801

Table 0807 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 8)

*Same as Table 0801

Table 0808 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 9)

*Same as Table 0801

Table 0809 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 10)

*Same as Table 0801

Table 0810 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 11)

*Same as Table 0801

Table 0811 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 12)

*Same as Table 0801

Table 0812 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 13)

*Same as Table 0801

Table 0813 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Physical Examination (Visit 1 vs. Visit 14)

*Same as Table 0801

9) Vital Sign

Analysis Set: Safety

Table 0901 Vital Sign Results and Change from Baseline (Temperature)

Time points		Medifoam	Betafoam	Total	P-value
Visit1(Screening)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Visit4~Visit13	..(Middle Part Omitted)..				
Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
Visit3-Visit1	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	p-value(within)	0.xxxx#			
[Visit4-Visit1]~ [Visit13-Visit1]	..(Middle Part Omitted)..				
Visit14-Visit1	N	xx	xx	xx	0.xxxx*
	Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
	Median	xx.xx	xx.xx	xx.xx	
	Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	p-value(within)	0.xxxx#			

Note) *: t-test, ￥: Wilcoxon rank sum test, #: Paired t-test, $: Wilcoxon signed rank test

Table 0902 Vital Sign Results and Change from Baseline (SBP, DBP, Pulse)

Variables	Time points		Medifoam	Betafoam	Total	P-value
SBP	Visit1(Screening)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit3(8d±1d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit4~Visit13	..(Middle Part Omitted)..				
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit3-Visit1	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
		p-value(within)	0.xxxx#			
	[Visit4-Visit1]~ [Visit13-Visit1]	..(Middle Part Omitted)..				
	Visit14-Visit1	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
		p-value(within)	0.xxxx#			
..DBP and Pulse sections are omitted in TLF..						

Note) *: t-test, ￥: Wilcoxon rank sum test, #: Paired t-test, $: Wilcoxon signed rank test

10) Laboratory Test

Analysis Set: Safety

Table 1001 Laboratory Test results and Change from Baseline (Hematology)

Variables	Time points		Medifoam	Betafoam	Total	P-value
WBC	Visit1(Screening)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit14-Visit1	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
..Rest Variables are omitted in TLF..						

Note) *: t-test, ￥: Wilcoxon rank sum test, #: Paired t-test, $: Wilcoxon signed rank test

Table 1002 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Laboratory Test (Hematology)

Visit1(Screening)		Visit14(85d±2d)											
		Medifoam						Betafoam					
		Normal		Abnormal		Total		Normal		Abnormal		Total	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
WBC	Normal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Abnormal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Total	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	(xx.xx)
P-value		0.xxxx						0.xxxx					
..Rest Variables are omitted in TLF..													

Note) Normal includes normal and NCS, while abnormal refers to CS.

Note) p-value: McNemar test

Table 1003 Laboratory Test results and Change from Baseline (Blood Chemistry)

Variables	Time points		Medifoam	Betafoam	Total	P-value
ALP	Visit1(Screening)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit14(85d±2d)	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
	Visit14-Visit1	N	xx	xx	xx	0.xxxx*
		Mean±Std	xx.xx±x.xx	xx.xx±x.xx	xx.xx±x.xx	
		Median	xx.xx	xx.xx	xx.xx	
		Min~Max	xx.xx~xx.xx	xx.xx~xx.xx	xx.xx~xx.xx	
..Rest Variables are omitted in TLF..						

Note) *: t-test, ￥: Wilcoxon rank sum test, #: Paired t-test, $: Wilcoxon signed rank test

Table 1004 Normal or Abnormal (NCS)/Abnormal(CS) cross table for Laboratory Test (Blood Chemistry)

Visit1 (Screening)		Visit14(85d±2d)											
		Medifoam						Betafoam					
		Normal		Abnormal		Total		Normal		Abnormal		Total	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
ALP	Normal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Abnormal	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)
	Total	xx	Xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	xx (xx.xx)	xx	(xx.xx)
P-value		0.xxxx						0.xxxx					
..Rest Variables are omitted in TLF..													

Note1) Normal includes normal and NCS, while abnormal refers to CS.

Note2) p-value: McNemar test

11) Adverse Events

Analysis Set: Safety

Table 1101 AE Summary (AE, ADE, SAE, SADE)

AE Type	Adverse Event	Treatment	n (Incidence rate)	95% C.I. of Incidence rate	Frequency	Total	P-value
Local	AE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	ADE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	SAE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	SADE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
Other	AE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	ADE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	SAE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	
	SADE	Medifoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	0.xxxx‡
		Betafoam	x(x.xx%)	(x.xx,x.xx)	xx	xx	
		Total	x(x.xx%)	(x.xx,x.xx)	xx	xx	

Note) ‡: Fisher's exact test

Table 1102 Number and Percentage of subjects with AE (SOC/PT*)

AE Type			Medifoam			Betafoam			Total		
			n	(%)	freq	n	(%)	freq	n	(%)	freq
Local	Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
	SOC	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
		PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
Other	Total		xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
	SOC	PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx
		PT	xx	(xx.xx)	xx	xx	(xx.xx)	xx	xx	(xx.xx)	xx

Note)* SOC: System Organ Class, PT: Preferred Term, * Coded in MedDRA Ver 18.1 or the latest version

Table 1103 Number and Percentage of subjects with ADE (SOC/PT)

*Same as Table 1102

Table 1104 Number and Percentage of subjects with SAE (SOC/PT)

*Same as Table 1102

Table 1105 Number and Percentage of subjects with SADE (SOC/PT)

*Same as Table 1102

Table 1106 Incidence rate, number and frequency of Local AE by Severity

Treatment Group	Severity	n (Incidence rate)	95% C.I. of Incidence rate	Frequency	Total
Medifoam	Mild	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Moderate	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Severe	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Total	x(x.xx%)	(x.xx,x.xx)	xx	xx
Betafoam	Mild	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Moderate	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Severe	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Total	x(x.xx%)	(x.xx,x.xx)	xx	xx

Table 1107 Incidence rate, number and frequency of Local AE by SAE

*Same as Table 1106

Table 1108 Incidence rate, number and frequency of Local AE by Outcome

*Same as Table 1106

Table 1109 Incidence rate, number and frequency of Local AE by Relationship

*Same as Table 1106

Table 1110 Incidence rate, number and frequency of Local AE by Action taken with the Device

*Same as Table 1106

Table 1111 Incidence rate, number and frequency of Local AE by Seriousness Criteria

*Same as Table 1106

Table 1112 Incidence rate, number and frequency of Other AE by Severity

	Severity	n (Incidence rate)	95% C.I. of Incidence rate	Frequency	Total
Medifoam	Mild	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Moderate	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Severe	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Total	x(x.xx%)	(x.xx,x.xx)	xx	xx
Betafoam	Mild	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Moderate	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Severe	x(x.xx%)	(x.xx,x.xx)	xx	xx
	Total	x(x.xx%)	(x.xx,x.xx)	xx	xx

Table 1113 Incidence rate, number and frequency of Other AE by SAE

*Same as Table 1112

Table 1114 Incidence rate, number and frequency of Other AE by Outcome

*Same as Table 1112

Table 1115 Incidence rate, number and frequency of Other AE by Relationship

*Same as Table 1112

Table 1116 Incidence rate, number and frequency of Other AE by Action taken with the Device

*Same as Table 1112

Table 1117 Incidence rate, number and frequency of Other AE by Seriousness Criteria

*Same as Table 1112