Statistical Analysis Plan (SAP)

FINS

Clinical Investigation Title:	Lower Extremity Fixation In Neuropathic Patients Study (FINS)
Device Name:	HOFFMANN® LRF SYSTEM SALVATION™ EXTERNAL FIXATION SYSTEM SALVATION™ FUSION BOLTS AND BEAMS SALVATION™ 2 MIDFOOT NAIL SALVATION™ 3DI PLATING SYSTEM T2® ICF SYSTEM VALOR™ ANKLE FUSION NAIL SYSTEM
Clinical Investigation Plan (CIP) Version:	3
Investigational Devices	HOFFMANN® LRF SYSTEM SALVATION™ EXTERNAL FIXATION SYSTEM SALVATION™ FUSION BOLTS AND BEAMS SALVATION™ 2 MIDFOOT NAIL SALVATION™ 3DI PLATING SYSTEM T2® ICF SYSTEM VALOR™ ANKLE FUSION NAIL SYSTEM
Indications	Detailed in the devices' Instructions for Use (IFU) and Surgical Technique Manual.
Clinical Investigation Design:	Prospective, observational, multi-site, multi-year post-market clinical follow-up study
Statistical Analysis Plan (SAP) Version:	1
Date:	14 – February- 2023
Confidentiality Statement:	This Statistical Analysis Plan contains confidential information, and its' use is limited to investigational staff intending to conduct the clinical investigation, Institutional Review Boards (IRBs)/Ethics Committees (ECs) and any others charged with reviewing the clinical investigation.

1 Administrative Information

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2 Table of Contents

3 List of Abbreviations and Definitions

Abbreviation	Explanation
AE(s)	Adverse Event(s)
CFR	Code of Federal Regulations
CI	Confidence Interval
CIP	Clinical Investigation CIP
CRF	Case Report Form
EC	Ethics Committee
FU	Follow-Up
EDC	Electronic Data Capture
EQ-5D-5L	A standardized health-related quality of life instrument by the EuroQuol Group
FAAM-SANE	Foot and Ankle Ability Measure-Single Assessment Numeric Evaluation
FDA	Food and Drug Administration
ITT	Intend-to-Treat Population
IQR	Interquartile Range
KM	Kaplan-Meier
LOCF	Last Observation Carried Forward
MEDRA	Medical Dictionary for Drug Regulatory Affairs
N (or n)	Total Sample Size (or subgroup sample size)
PMA	Pre-Market Authorization
PMCF	Post-Market Clinical Follow-Up
PP	Per Protocol Population
PROM	Patient Reported Outcome Measures
QoL	Quality of Life
OR	Odds Ratio
RR	Relative Risk
SADE(s)	Serious Adverse Device Effect(s)
SAE(s)	Serious Adverse Event(s)
SAF	Safety Population
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
UADE(s)	Unanticipated Adverse Device Effect(s)
USADE(s)	Unanticipated Serious Adverse Device Effect(s)

Term	Definition
Adverse Event	Any untoward medical occurrence in patients/subjects, users or other persons. In the context of clinical investigation, for patients/subjects, this would include all untoward medical occurrences, whether or not related to the investigational device, that occurred in the course of the investigation. In the context of clinical experience, this would only include untoward medical occurrences that may be related to the medical device.
Clinical Performance	The ability of a medical device to achieve its intended clinical purpose as claimed by the manufacturer.

4 Introduction

4.1 Background and Rationale

This statistical analysis plan is developed to provide the analytic framework and the production of statistical output of the FIN Study. This analysis plan is based on the FINS CIP version 3, dated 27 April 2022. The FIN Study was a prospective, multisite, multiyear, post-market follow-up clinical (PMCF) investigation that aimed to compare the pooled three-year amputation rate of the investigational devices in **Table 1** to a performance goal derived from a literature-based source. The study planned to enroll at least 200 subjects at 10 sites in the US, however, the Sponsor decided to discontinue the enrollment on 28 October 2022. Approximately 42 subjects were implanted with at least one investigational device when the study was discontinued. This statistical plan will guide the statistical analysis and presentation of these subjects that were enrolled and implanted with any of the devices under investigation.

Table 1. Study Device FDA 510K Clearance Information

Device Name	Date of Clearance	510K Number
HOFFMANN® LRF SYSTEM	01Feb2021	K203568
SALVATION™ EXTERNAL FIXATION SYSTEM	06Jun2018	K180832
SALVATION™ FUSION BOLTS AND BEAMS	21Mar2014	K140741
SALVATION™ 2 MIDFOOT NAIL	11Jul2018	K180024
SALVATION™ 3DI PLATING SYSTEM	22May2014	K140792
SALVATION™ OSTEOPENIC SCREW	14May2014	K140408
T2® ICF SYSTEM	20Mar2020	K193366
VALOR™ ANKLE FUSION NAIL	22Oct2014	K142602

4.2 Clinical Investigation Purpose

The Sponsor identified a need to collect PMCF data to verify the safety and efficacy/performance of the HOFFMANN® LRF SYSTEM, SALVATION™ EXTERNAL FIXATION SYSTEM, SALVATION™ FUSION BOLTS AND BEAMS, SALVATION™ 2 MIDFOOT NAIL, SALVATION™ 3DI PLATING SYSTEM, T2® ICF SYSTEM, and VALOR™ ANKLE FUSION NAIL Systems. The study was initiated to demonstrate the safety and performance/efficacy of these systems using the data collected. The study planned to assess efficacy through the 3-year amputation rate. Safety was to be assessed through the incidence of device-related intra-operative and post-operative adverse events/incidents (AEs) by 5 years. The study planned to follow all subjects annually post-operatively for 5 years.

5 Clinical investigation Objectives and Endpoints

The primary effectiveness hypothesis is that the 3-year amputation rate (including both above and below the knee) is less than the performance goal (PG).

5.1 Primary Endpoints

The primary endpoint of the study was the overall performance of the devices (HOFFMANN® LRF SYSTEM, SALVATION™ EXTERNAL FIXATION SYSTEM, SALVATION™ FUSION BOLTS AND BEAMS, SALVATION™ 2 MIDFOOT NAIL, SALVATION™ 3DI PLATING SYSTEM, T2® ICF SYSTEM, and VALOR™ ANKLE FUSION NAIL Systems) measured as the 3-year amputation rate.

5.2 Secondary Endpoints

The secondary performance endpoints were:

- Improvement in patient-reported function, and social interaction for quality of life via
  - EuroQuol five dimensions (EQ-5D-5L); and
  - Foot and Ankle Ability Measure (FAAM).
- Performance or survival of the device measured as the 5-year Amputation Rate

The secondary safety endpoints were:

- incidence and rate of AEs through 5 years;
- physical and radiographic assessment of the implant status; and
- rate of surgical Intervention

5.3 Other Exploratory Endpoints

None

6 Clinical Investigation Methods

This investigation was a prospective, multicenter PMCF study. The clinical investigation was designed to follow the surgeon's standard of care for the treatment of deformity in the neuropathic patient over 5 years.

6.1 General Clinical Investigation Design and Plan

This study was designed to clinically assess over time the effectiveness and safety of the devices under investigation. There was no randomization of subjects employed. The study did not employ any methods (e.g., randomization, blinding, or stratification) for assigning subjects. Consecutive subjects at each site that met all the eligibility criteria were invited to enroll in the study. The study planned to collect data from subjects before implant surgery, during the procedure, 6 months post-operative and annually thereafter for five years. Demographic factors, Medical History, and disease state were collected at baseline. The patient-reported outcomes, EQ-5D-5L and FAAM were collected at baseline, at 6 months post-operative and at scheduled annual post-surgery visits to evaluate improvement in pain, function, social interaction, and quality of life. Safety of the implants in terms of complications and adverse events that occurred during the study was collected.

6.2 Inclusion-Exclusion Criteria

Subjects that met the following inclusion criteria were invited to be enrolled in the study.

a. Subject was a male or non-pregnant female age 18 years or older at the time of surgery;
b. Subject was willing and able to give written informed consent and comply with the requirements of the Clinical Investigation Plan (CIP); and
c. Subject had neuropathy and intended to be treated for deformity with the one or a combination of the below Systems in accordance with the legally cleared/ approved IFU and Surgical Technique Manual.
    - HOFFMANN® LRF SYSTEM
    - SALVATION™ EXTERNAL FIXATION SYSTEM
    - SALVATION™ FUSION BOLTS AND BEAMS
    - SALVATION™ 2 MIDFOOT NAIL
    - SALVATION™ 3DI PLATING SYSTEM
    - T2® ICF SYSTEM
    - VALOR™ ANKLE FUSIO NAIL SYSTEM

Subjects that were

a. determined, by the investigator, to be an inappropriate candidate for the procedure indicated; or
b. unable to consent to participate (written, informed consent); or
c. unable to attend/complete the requested follow-up visits

were excluded from the study

6.3 Withdrawal / Follow-up

The study allowed subjects to withdraw from the clinical investigation for any of the following reasons:

a. Voluntary withdrawal by the subject;
b. Subject was Lost to Follow-Up (LTFU);
c. Amputation below the knee or above the knee;
d. Adverse event that prohibited the subject from continued participation;
e. Subject non-compliance to study protocol; and
f. Other reason(s) that may have exposed the subject to unacceptable risk.

6.4 Methods to Minimize Bias and Confounding Factors

The study design did not employ a method for assigning subjects. A consecutive series of subjects at each site meeting all the eligibility criteria were enrolled in the study.

6.5 Clinical Investigation Assessments

The study collected subject data at baseline, surgery, 6 months, 1 year, and at 2-5 years post-surgery follow-up visits. The follow-up evaluations included the patient-reported outcome measures: EQ-5D-5L and FAAM, adverse events, and occurrence of surgical intervention. Refer to **Table 2** below for the visit windows and the list of assessments performed at each visit as indicated in the CIP. There will be no windowing of days elapsing from surgery to a visit date and the determination of post-operative visit will be based on the visit completed indicated in the study form.

Table 2. Schedule of Events

Assessment	Pre-Operative	Operative/ Discharge	6 months [a, b] (+/-3 months)	1 Year [a, b] (+/-6 months)	2-5 years [a, b] (+/-6 months)	Study Close
Informed Consent	X					
Inclusion/Exclusion	X					
Demographics & Medical History	X					
Disease State Pre-Op	X					
EQ-5D-5L	X		X	X	X	
FAAM	X		X	X	X	
Surgical Procedure		X				
Investigator Assessment			X	X	X	
Adverse Event Assessment		X	X	X	X	
Staged Operative Information [d]						
Surgical Intervention [d]						
Subject Disposition [c]						X

a. Follow-up visit schedule to reflect Institutions' Standard of Care practices.
b. If the subject missed a visit and is outside of visit window, every effort should be made to collect data instead of noting visit as missed.
c. Subject Disposition assessment will occur at any time point for subject withdrawal prior to the completion of the clinical investigation.
d. These are not scheduled time point events but will be observed throughout the study participation

6.6 Sample Size

The study required a sample size of 141 patients to provide at least 80% statistical power to reject the hypothesis that the 3-year amputation rate is less than the PG with a significance α=0.05. However, this sample size requirement was not met at to study discontinuation.

7 General Analysis Considerations

Data will be summarized for each of the devices listed in **Table 1**. Because the study was prematurely terminated, all analysis will be descriptive only. All analyses will be done to summarize all available data. No statistical hypothesis testing will be implemented.

7.1 Timing of Analyses

Statistical summaries will be implemented for the final data, that is, all data collected in the study.

7.2 Analysis Populations

All subjects who received any clinical investigation treatment/device upon study termination are included in the ITT and safety population.

7.3 Covariates and Subgroups

No subgroup analysis will be conducted.

7.4 Multicenter Clinical investigations

Except for the study site distribution of subjects, no center specific analysis will be conducted.

7.5 Missing Data

No imputation of missing data will be conducted.

7.6 Multiple Testing/Comparison

No test of hypothesis will be conducted.

7.7 Conventions

In the case of collection of variables with non-SI units (e.g., pounds instead of kilograms), conversion of such data into SI units (and vice versa) will be ensured. The data for both SI and non-SI units will be reported in the final listing of data. Differences between score results will be calculated.

8 Summary of Clinical Investigation Data

The statistical analysis will be implemented to summarize the data collected upon study termination. All data will be summarized by visit and by device, whenever possible. Categorical and ordinal data will be displayed as frequency and percent. Continuous data will be summarized with the following summary statistics (number of observations, mean, median, standard deviation, inter-quartile range, minimum, and maximum).

8.1 Subject Disposition

Distribution of subjects by investigational device and overall will be presented. Also, the site distribution of subjects by, visit completion and the reason for study non-completion will be presented.

8.2 Subject Accounting

The subject accounting will present the frequency of subjects that are expected for follow-up, the rate of actual follow-up and the assessment of visit compliance.

8.3 CIP Deviations

The extent of protocol deviations that occurred in the study will be presented. CIP deviations that could impact the analysis will not be assessed.

8.4 Demographics and Disease pre-operative state

The demographic factors: gender (M/F), age (years), smoking status, body mass index (BMI), race, diabetes status, and disease state. Pre-operative disease state variables included: Brodsky/Trepman Classification, Pre-operative state (walking or with aids), pain level, presence of a chronic ulcer, infection, insulin use, type peripheral neuropathy, revascularization history, peripheral artery disease retinopathy, and chronic kidney disease.

8.5 Operative Variables

The following surgical information will be summarized: indication for implant use, operative side (left or right), previous surgery to index procedure, biologics use, and intraoperative complications.

9 Summary of Effectiveness/Performance Data

EuroQol (EQ-5D-5L)

A generic health survey can be used to compare improvement across different interventions and measure changes in health-related quality of life over time. The EQ-5D-5L comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and 100 on VAS indicates the best health, whereas 0 on the VAS indicates the worst health. Patient health profiles with concerning mobility, self-care, activities, pain/discomfort and anxiety/depression will be presented as frequency and rates. In addition, the summaries for improvement from baseline in VAS health score will be presented. Also, summaries for the converted EQ-5D-5L index value will be presented. At each post-surgery follow-up visit, descriptive statistics and confidence interval estimates of the mean will be constructed for the change in scores.

FAAM

The Foot and Ankle Ability Measure (FAAM) is a self-report outcome instrument to assess physical function for individuals with foot and ankle-related impairments. The FAAM consists of 29-item questions divided into two subscales: 21-item activities of daily living (ADL) subscale, an 8-item sports subscale. Each item is scored on a 5-point Likert scale (4 to 0) from 'no difficulty at all' to 'unable to do'. Responses of “not applicable” are not counted. The scores of the sub-scale items will be added together to get the subscale total score. The ADL subscale total score ranges from 0 to 84, and 0 to 32 for the sports subscale. The patient score for the ADL and sports subscale will be transformed into percentage scores by considering the highest possible score for non-missing items. A higher score indicates a higher level of function for each subscale, with 100% representing no dysfunction (Martin et al., 2009).

Surgeon Assessment and radiographic outcome

The attending surgeon assessed the outcome of the implant one year after surgery and at the final visit. The following factors were assessed by the surgeon:

- Insulin use
- Ulcer healing and presence of new ulcers
- Presence of new deep infection
- Ankle alignment status
- Current mobility status (walking, use of mobility aids)

In addition, radiographic assessment of deformity correction was collected. The surgeon assessment of angle deformity correction based on radiograph will be summarized for the following:

- Meary's angle deformity: Lateral & AP;
- Talonavicular angle; and
- Cuboid height (mm)

9.1 Primary Effectiveness/Performance Analysis

None of the subjects reached their three-year post-surgery follow-up. Thus, the three-year amputation rate, which is the primary endpoint will not be analyzed. Instead, the frequency of amputations at each post-surgery visit will be presented. The status of the subject at the latest follow-up, coded as either walking, use of mobility aids, bedridden or having amputation will be summarized instead.

9.2 Analyses of Secondary Effectiveness Endpoints

EQ-5D-5L and FAAM scores will be summarized at each visit. In addition, score improvement at each post-operative visit will also be summarized by the change from baseline score in EQ-5D-5L and FAAM total and their component scores. Also, the post-operative physical and radiographic assessment of the surgical foot and the implant by the investigator will be summarized.

10 Safety Analyses

The safety data will be summarized by the frequency and percentage of AE incidence. Each AE was also assessed according to the relationship to the clinical investigation device and severity.

10.1 Adverse Events

The safety of each device will be summarized in the final report. The overall summary of adverse events will be presented for each device. Total events, patient counts and percentages of adverse events for each device will be summarized for the following factors:

i.) Procedure-Related Adverse Event / Incident.
ii.) Device-Related Adverse Event / Incident
iii.) Device Failure
iv.) Serious Adverse Event (SAE)
v.) Hospitalization SAE Outcome
vi.) Treatment Required for the AE

10.2 Serious Adverse Events

A separate summary table (or listing) of complications that met the serious adverse events (SAE) classification will be presented. Also, this section presents the narratives of each SAE that occurred in the clinical investigation. A serious adverse event (SAE) as defined from ISO 14155:2020(E) Clinical Investigations of Medical Devices for Human Subjects – Good clinical practice, is any adverse event that:
a. Led to death,

b. Led to a serious deterioration in the health of the subject, that either resulted in

- A life-threatening illness or injury, or
- A permanent impairment of a body structure or a body function, or
- In-patient or prolonged hospitalization, or
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.

c. Led to fetal distress, fetal death or congenital abnormality or birth defect.

The narrative for each SAE will be presented to describe the following:

- Nature and intensity of the event,
- Clinical course leading up to the event,
- Indication of timing relevant to test investigational device/product administration,
- Relevant laboratory measurements;
- Whether the treatment was stopped, and countermeasures (and timing);
- Post-mortem findings;
- Investigator's opinion on causality and sponsor's opinion on causality, if appropriate.

In addition, the following information will be included (if available) in the SAE narrative:

- Patient identifier;
- Age and sex of patient; general clinical condition of the patient, if appropriate;
- Disease being treated (this is not required if it is the same for all patients) with duration (of the current episode) of illness;

11 Reporting Conventions

All statistical output will have the following standard elements:

Stryker Corporation US-20-SAL-001-FINS Page __ of __ Title of Display Clinical investigation Population <BODY OF DISPLAY> Data Version: <date9> <program name> Execution date: <date9> Listing Reference: <Listing #>

12 Summary of Changes to the CIP and/or SAP

No changes to the planned statistical analysis as indicated in the CIP.

13 Statistical Software

All statistical analyses will be performed using SAS version 14.1 or higher.

14 Listing of Tables, Listings, and Figures (TLF)

The listings of TLF are provided below with the link to the corresponding Table templates in Appendix 1.

14.1 Listing of Tables

14.2 Listing of Listings

14.3 Listing of Figures

No figures will be presented.

15 References and Related Documents

Domsic RT, Saltzman CL. Ankle osteoarthritis scale. *Foot Ankle Int.* 1998; 19:466-471 EQ5D-5L Questionnaire; EQ-5D™ is a trade mark of the EuroQol Research Foundation.

Maher, A, Kilmartin, T. An analysis of Euroqol EQ5D and Manchester Oxford Foot Questionnaire. *Journal of Foot and Ankle Research* 2012; 5; 7

Martin RL, Hutt DM, Wukich DK. Validity of the Foot and Ankle Ability Measure (FAAM) in Diabetes Mellitus. Foot Ankle Int. 2009 Apr;30(4):297-302

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Lower Extremity Fixation In Neuropathic Patients Study (FINS) Clinical Investigation Plan. Version 3 27-APR-2022

15.1 All Table Shells

Table 1.1 Subject Disposition – ITT

Device	Pre-Op	Final F-up (Op- 1yr)	Post-Op (1 yr.)
SALVATION™ 3Di Plating			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			
SALVATION™ External Fixation			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			
SALVATION™ Fusion Bolts and Beams			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			
SALVATION™ MIDFOOT NAIL			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			

Device	Pre-Op	Final F-up (Op- 1yr)	Post-Op (1 yr.)
VALOR™ Nail			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			
HOFFMANN® LRF SYSTEM			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			
T2® ICF SYSTEM			
Total			
Available Data			
Reason for Discontinuation			
Subject lost to follow-up			
Subject withdrew consent			
Adverse Event			
Other			

Table 1.2 Subject Eligibility

	Inclusion Questions			Exclusion Questions			Eligible
	1	2	3	1	2	3	
All Subjects							
By Device							
SALVATION™ 3Di Plating							
SALVATION™ Fusion Bolts and Beams							
SALVATION™ External Fixation							
SALVATION™ MIDFOOT NAIL							
VALOR™ Nail							
Total							

Note:
Inclusion 1 - Subject is a male or non-pregnant female age 18 years or older at the time of surgery;
Inclusion 2 - Subject is willing and able to give written informed consent and comply with the requirements of this Clinical Investigation Plan (CIP); and
Inclusion 3 - Subject has or is intended to be treated for neuropathy with the one or a combination of the below Systems in accordance with the legally cleared/ approved IFU and Surgical Technique Manual.
o HOFFMANN® LRF SYSTEM
o SALVATION™ EXTERNAL FIXATION SYSTEM
o SALVATION™ FUSION BOLTS AND BEAMS
o SALVATION™ 2 MIDFOOT NAIL
o SALVATION™ 3DI PLATING SYSTEM
o T2® ICF SYSTEM
o VALOR™ ANKLE FUSIO NAIL SYSTEM
Exclusion 1 – Subjects determined, by the investigator, to be an inappropriate candidate for the procedure indicated;
Exclusion 2 - Unable to consent to participate (written, informed consent);
Exclusion 3 - Unable to attend/complete the requested follow-up visits

Table 1.3 Subject Accounting and Follow-up Compliance – ITT

Device	Pre-op	1 Year	Final Visit
	N	N	N
SALVATION™ 3Di Plating System			
Theoretical			
Deaths (cumulative)			
Failures (cumulative)			
Withdrawn (cumulative)			
Expected			
Actual[1]			
% Follow-up[1]			
EQ-5D Score			
FAAM Score			
SALVATION™ External Fixation			
Theoretical			
Deaths (cumulative)			
Failures (cumulative)			
Withdrawn (cumulative)			
Expected			
Actual[1]			
% Follow-up[1]			
EQ-5D Score			
FAAM Score			
SALVATION™ Fusion Bolts and Beams			
Theoretical			
Deaths (cumulative)			
Failures (cumulative)			
Withdrawn (cumulative)			
Expected			
Actual[1]			
% Follow-up[1]			
EQ-5D Score			
FAAM Score			
SALVATION™ MIDFOOT NAIL			
Theoretical			
Deaths (cumulative)			
Failures (cumulative)			
Withdrawn (cumulative)			
Expected			
Actual[1]			
% Follow-up[1]			
EQ-5D Score			
FAAM Score			
VALOR™ Nail			
Theoretical			
Deaths (cumulative)			
Failures (cumulative)			

Withdrawn (cumulative)			
Expected			
Actual[1]			
% Follow-up[1]			
EQ-5D Score			
FAAM Score			
[1]*Any data point available at follow-up*			

Table 1.4 CIP Deviations

	Type of Deviation				
	Dev 1	**Dev 2**	**Dev 3**	**Dev 4**	**Total Deviations**
All Subjects (N=114)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
SALVATION™ 3Di Plating System	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
SALVATION™ External Fixation	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
SALVATION™ Fusion Bolts and Beams	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
SALVATION™ MIDFOOT NAIL	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
VALOR™ Nail	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx

Table 1.5 Demographic and Baseline Variables

Factors	Freq(%)
Gender	
Male	xx(xx.xx%)
Female	xx(xx.xx%)
Race	
African-American/Black	xx(xx.xx%)
Asian	xx(xx.xx%)
Hispanic/Latino	xx(xx.xx%)
Native American/Alaskan	xx(xx.xx%)
Native Hawaiian/Pacific Islander	xx(xx.xx%)
White	xx(xx.xx%)
Other	xx(xx.xx%)
Smoking Status	
Never	xx(xx.xx%)
Previous	xx(xx.xx%)
Current, <= 1 Pack/day	xx(xx.xx%)
Current, > 1 pack/day	xx(xx.xx%)

Factors	n	mean	std	min	max	median (IQR)	95% CI
Age at Rx (years)	xx	xx.xx	xx.xx	xx.x	xx.x	xx.x(xx.x,xx.x)	(xx.x,xx.x)
Height (cm)	xx	xx.xx	xx.xx	xx.x	xx.x	xx.x(xx.x,xx.x)	(xx.x,xx.x)
Weight (kg)	xx	xx.xx	xx.xx	xx.x	xx.x	xx.x(xx.x,xx.x)	(xx.x,xx.x)
BMI (kg/m)	xx	xx.xx	xx.xx	xx.x	xx.x	xx.x(xx.x,xx.x)	(xx.x,xx.x)

Table 1.6 Medical History at Screening

	All Subjects N=xx
Any Concomitant Health Conditions	
No	xx(xx.xx%)
Yes	xx(xx.xx%)
Autoimmune	xx(xx.xx%)
Cardiovascular	xx(xx.xx%)
Respiratory	xx(xx.xx%)
Gastrointestinal	xx(xx.xx%)
Hematological	xx(xx.xx%)
Psychological	xx(xx.xx%)
Musculoskeletal	xx(xx.xx%)
Neurological	xx(xx.xx%)
Endocrine	xx(xx.xx%)
Skin/Subcutaneous Tissue	xx(xx.xx%)
Peripheral Vascular Disease	xx(xx.xx%)
Diabetes	
Type I	xx(xx.xx%)
Type II	xx(xx.xx%)
Other Health Conditions	
No	xx(xx.xx%)
Yes	xx(xx.xx%)

Table 1.7 Pre-operative Disease State

	SALVATION™ 3Di Plating (N=xx)	SALVATION™ External Fixation (N=xx)	SALVATION™ Fusion Bolts and Beams (N=xx)	SALVATION™ MIDFOOT NAIL (N=xx)	VALOR™ Nail (N=xx)
Brodsky/Trepman Classification					
Type 1: Midfoot	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Type 2: Hindfoot	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Type 3a: Ankle	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Type 3b: Calcis tubercle	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Type 4: Combination	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Type 5: Forefoot	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Pre-operative state					
Walking with					
Custom shoes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Bracing	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
CROW boots	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Other	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Aids					
None	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Cane	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Walker	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Knee scooter	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Level of Pain					
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
Ulcer					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Chronic Ulcer					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Deep Infection					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Insulin use					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Peripheral neuropathy, type					
Congenital	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Diabetes Mellitus	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Idiopathic/Unknown	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Post-Traumatic	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Peripheral artery disease					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
History of revascularization					

	SALVATION™ 3Di Plating (N=xx)	SALVATION™ External Fixation (N=xx)	SALVATION™ Fusion Bolts and Beams (N=xx)	SALVATION™ MIDFOOT NAIL (N=xx)	VALOR™ Nail (N=xx)
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Peripheral artery disease					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Retinopathy					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Chronic kidney disease					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)

Table 2.1 Operative Information

	ORTHOLOC™ 3Di Midfoot/Flatfoot	SALVATION™ External Fixation (N=xx)	SALVATION™ Fusion Bolts and Beams (N=xx)	SALVATION™ MIDFOOT NAIL (N=xx)	VALOR™ Nail (N=xx)
Indications for Use					
Post traumatic	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Arthritis	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Fracture	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Fusion	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Reconstruction/Correction	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Revision procedure	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Instability	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Skeletal defect	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Previous Surgery to Index procedure					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Operative Side					
Left	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Right	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Wright Biologics use					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Intra-operative complication					
No	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Yes	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)

Table 3.1 EQ-5D Score

	Baseline				Final Visit				1 Yr. Visit			
	n	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**
SALVATION™ Fusion Bolts and Beams												
EQ-VAS Score	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
EQ-VAS Score					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ MIDFOOT NAIL												
EQ-VAS Score	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	Xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
EQ-VAS Score					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ 3Di Plating System												
EQ-VAS Score	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
EQ-VAS Score					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
VALOR™ Nail												
EQ-VAS Score	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
EQ-VAS Score					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ External Fixation												
EQ-VAS Score	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
EQ-VAS Score					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
EQ-5D Index					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx

Table 3.2 FAAM Score

	Baseline				Final Visit				1 Yr. Visit			
	n	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**
SALVATION™ Fusion Bolts and Beams												
FAAM SANE	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
FAAM SANE					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ MIDFOOT NAIL												
FAAM SANE	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	Xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
FAAM SANE					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ 3Di Plating System												
FAAM SANE	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
FAAM SANE					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
VALOR™ Nail												
FAAM SANE	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
FAAM SANE					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx

	Baseline				Final Visit				1 Yr. Visit			
	n	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**	**n**	**Mean ± SD**	**min,max**	**95% CI**
Sports Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
SALVATION™ External Fixation												
FAAM SANE	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale	xx	xx.x ± xx.x	xx.x , xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Change from Baseline												
FAAM SANE					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
Sports Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx
ADL Subscale					xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx.x	xx	xx.x ± xx.x	xx.x, xx.x	xx.x, xx

SANE -Single Assessment Numeric Evaluation.

Table 3.3 Surgeon Assessment

Device	Factors	1 Year Visit		Final Visit	
		N	%	N	%
SALVATION™ Fusion Bolts and Beams	**Insulin Use**				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ulcers	New Ulcer		Ulcer Healing	
	Yes	xx	xx.x%	xx	xx.x%
	No	xx	xx.x%	xx	xx.x%
	Chronic Ulcer				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	New Deep Infection				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ankle Alignment				
	Acceptable			xx	xx.x%
	Unacceptable			xx	xx.x%
	Not applicable			xx	xx.x%
	Current Status				
	Walking	xx	xx.x%	xx	xx.x%
	Mobility with aids	xx	xx.x%	xx	xx.x%
	Wheelchair	xx	xx.x%	xx	xx.x%
	Bed ridden	xx	xx.x%	xx	xx.x%
	Amputation	xx	xx.x%	xx	xx.x%
SALVATION™ Midfoot Nail	**Insulin Use**				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ulcers	New Ulcer		Ulcer Healing	
	Yes	xx	xx.x%	xx	xx.x%
	No	xx	xx.x%	xx	xx.x%
	Chronic Ulcer				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	New Deep Infection				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ankle Alignment				
	Acceptable			xx	xx.x%
	Unacceptable			xx	xx.x%
	Not applicable			xx	xx.x%
	Current Status				
	Walking	xx	xx.x%	xx	xx.x%
	Mobility with aids	xx	xx.x%	xx	xx.x%

Device	Factors	1 Year Visit		Final Visit	
		N	%	N	%
	Wheelchair	xx	xx.x%	xx	xx.x%
	Bed ridden	xx	xx.x%	xx	xx.x%
	Amputation	xx	xx.x%	xx	xx.x%
SALVATION™ 3Di Plating System	**Insulin Use**				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ulcers	New Ulcer		Ulcer Healing	
	Yes	xx	xx.x%	xx	xx.x%
	No	xx	xx.x%	xx	xx.x%
	Chronic Ulcer				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	New Deep Infection				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ankle Alignment				
	Acceptable			xx	xx.x%
	Unacceptable			xx	xx.x%
	Not applicable			xx	xx.x%
	Current Status				
	Walking	xx	xx.x%	xx	xx.x%
	Mobility with aids	xx	xx.x%	xx	xx.x%
	Wheelchair	xx	xx.x%	xx	xx.x%
	Bed ridden	xx	xx.x%	xx	xx.x%
	Amputation	xx	xx.x%	xx	xx.x%
VALOR™ Nail	**Insulin Use**				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ulcers	New Ulcer		Ulcer Healing	
	Yes	xx	xx.x%	xx	xx.x%
	No	xx	xx.x%	xx	xx.x%
	Chronic Ulcer				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	New Deep Infection				
	Yes	xx	xx.x%		
	No	xx	xx.x%		
	Ankle Alignment				
	Acceptable			xx	xx.x%
	Unacceptable			xx	xx.x%
	Not applicable			xx	xx.x%

Device	Factors	1 Year Visit		Final Visit	
		N	**%**	**N**	**%**
	Current Status				
	Walking	xx	xx.x%	xx	xx.x%
	Mobility with aids	xx	xx.x%	xx	xx.x%
	Wheelchair	xx	xx.x%	xx	xx.x%
	Bed ridden	xx	xx.x%	xx	xx.x%
	Amputation	xx	xx.x%	xx	xx.x%

Table 3.4 Radiographic Assessment

	Pre-operative						Final Visit						Improvement					
	n	**mean**	**sd**	**min**	**max**	**95% CI**	**n**	**mean**	**sd**	**min**	**max**	**95% CI**	**n**	**mean**	**sd**	**min**	**max**	**95% CI**
SALVATION™ 3Di Plating System																		
AP Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Lateral Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Talonavicular Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Cuboid height (mm)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
SALVATION™ External Fixation																		
AP Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Lateral Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Talonavicular Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Cuboid height (mm)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
SALVATION™ Fusion Bolts and Beams																		
AP Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Lateral Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Talonavicular Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Cuboid height (mm)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
SALVATION™ MIDFOOT NAIL																		
AP Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Lateral Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Talonavicular Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Cuboid height (mm)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Valor™ Nail																		
AP Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Lateral Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Cuboid height (mm)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)
Talonavicular Meary's Angle	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)	xx	xx.x	x.x	xx	xx	(xx.x, xx.x)

Table 4.1 Summary of All Adverse Events

	SALVATION™ Fusion Bolts and Beams (N = xx)		**SALVATION™ MIDFOOT NAIL (N = xx)**		**SALVATION™ External Fixation (N = xx)**		**SALVATION™ 3Di Plating System (N = xx)**		**VALOR™ Nail (N = xx)**	
	Subjects	**Event**	**Subjects**	**Event**	**Subjects**	**Event**	**Subjects**	**Event**	**Subjects**	**Event**
Total	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Procedure-Related	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Device-Related	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Device Failure	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
UADE	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Unanticipated AE	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Serious AE	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Hospitalization	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Death	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Required Treatment**	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Physical Therapy	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Medication	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Surgery	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx
Other	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx	xx(xx.x%)	xx

Table 4.2 Device-related Adverse Events

Subject ID	Age	Gender	Device(s)	Device Indication	Onset Days	Event Description	Device Failure (Y/N)	UADE (Y/N)	Surgery date

Table 4.3 Serious Adverse Events

Subject ID	Age	Gender	Device	Device Indication	SAE Onset Days	Event Description	Outcome

DocuSign

Certificate Of Completion

Envelope Id: 215FCFE3E56841B4B41B5DC7E89E9D7A
Status: Completed
Subject: Complete with DocuSign: FINS US-20 SAL-001 Statistical Analysis Plan 6Jan2023-Final.pdf
Source Envelope:
Document Pages: 36
Signatures: 4
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Envelope Originator:
Jovi Quiton
jovelyn.quiton@stryker.com
IP Address: 104.4.253.93

Record Tracking

Status: Original
2/14/2023 5:36:56 AM

Holder: Jovi Quiton
jovelyn.quiton@stryker.com

Location: DocuSign

Signer Events	Signature	Timestamp
David Fitch david.fitch@stryker.com Security Level: Email, Account Authentication (None)	DocuSigned by: David Fitch E1459B1F4E7B4D1... Signature Adoption: Pre-selected Style Using IP Address: 4.31.14.131	Sent: 2/14/2023 5:41:29 AM Resent: 2/22/2023 7:16:09 AM Viewed: 2/22/2023 7:17:07 AM Signed: 2/22/2023 7:17:16 AM
Electronic Record and Signature Disclosure: Accepted: 9/20/2022 9:15:51 AM ID: 193d2803-eb49-4082-9f74-157c1f9d2a2e		
Jovi Quiton jovelyn.quiton@stryker.com Senior Manager, Statistics Security Level: Email, Account Authentication (None)	DocuSigned by: 74CDF10AA94943E... Signature Adoption: Uploaded Signature Image Using IP Address: 104.4.253.93	Sent: 2/14/2023 5:41:30 AM Viewed: 2/22/2023 7:14:54 AM Signed: 2/22/2023 7:15:03 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Monica Fleeman monica.fleeman@stryker.com Sr. Clinical Study Manager Stryker Security Level: Email, Account Authentication (None)	DocuSigned by: Monica Fleeman 9D851D9BB8FC415... Signature Adoption: Pre-selected Style Using IP Address: 76.214.178.82	Sent: 2/14/2023 5:41:29 AM Viewed: 2/14/2023 6:23:25 AM Signed: 2/14/2023 6:23:31 AM
Electronic Record and Signature Disclosure: Accepted: 2/14/2023 6:23:25 AM ID: 16e7aa87-dfcb-4baf-9f00-e3bcc981096f		
Rebecca Gibson Rebecca.Gibson@stryker.com Director, Clinical Operations Stryker Corporation - Trauma & Extremitites Security Level: Email, Account Authentication (None)	DocuSigned by: Rebecca Gibson B69B71B0C1FA437... Signature Adoption: Pre-selected Style Using IP Address: 206.74.115.202	Sent: 2/14/2023 5:41:30 AM Viewed: 2/15/2023 4:25:45 PM Signed: 2/15/2023 4:28:44 PM
Electronic Record and Signature Disclosure: Accepted: 8/30/2022 7:58:43 AM ID: ba2910e0-ad1a-4548-88ee-9a3a66121c1a		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp
Agent Delivery Events	**Status**	**Timestamp**
Intermediary Delivery Events	**Status**	**Timestamp**
Certified Delivery Events	**Status**	**Timestamp**
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/14/2023 5:41:30 AM
Certified Delivered	Security Checked	2/15/2023 4:25:45 PM
Signing Complete	Security Checked	2/15/2023 4:28:44 PM
Completed	Security Checked	2/22/2023 7:17:16 AM

Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

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