Wright Foot & Ankle Post-Market Observational Study
Statistical Analysis Plan (SAP)

CLINICAL INVESTIGATION TITLE:	Wright Foot & Ankle Post-Market Observational Study
DEVICE NAME:	611 Nail BIOARCH BIOFOAM Ankle Spacer BIOFOAM Wedge System CHARLOTTE MUC Screws CHARLOTTE Quick Staple CHARLOTTE Snap-Off Screws CLAW II DARCO Headed Rearfoot Screws DARCO Headed Screws DARCO Headless Screws DARCO MFS DARCO MRS DARCO Plantar Lapidus Plate DART-FIRE FUSEFORCE FUTURA CSI G-FORCE GRAVITY SYNCHFIX HV Screws MaxLock Edgelock Plate MiniMaxLock ISO Plate MICA Screws NEXFIX Snap-Off Screws Omni Evolution Screws ORTHOLOC 2 Ankle Fracture ORTHOLOC 2 CROSSCHECK ORTHOLOC 2 Small Bones ORTHOLOC 3Di Ankle Fusion ORTHOLOC 3Di Hallux ORTHOLOC 3Di Midfoot/Flatfoot ORTHOLOC Forefoot Fracture ORTHOLOC Plantar Lapidus ORTHOLOC Calc Fracture PHALINX PITON PRO-TOE VO SALVATION ExFix SALVATION Bolts and Beams SALVATION 3Di Plates SWANSON Toes Telya UNIMA EVO and NEUTRA Screws VALOR Nail
STATISTICAL ANALYSIS PLAN (SAP) VERSION:	1
CLINICAL INVESTIGATION PLAN (CIP) VERSION:	2
ClinicalTrials.Gov	NCT04118894

INDICATIONS:	The Instructions for Use (IFU) for each individual product can be found at http://www.wright.com/prescribing-use-3.
CLINICAL INVESTIGATION DESIGN:	• Post-Market, • Multicenter, • Prospective, • Non-Randomized
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.
DATE:	07-Dec-2021

Approval Page

APPROVERS			
Role	**Name**	**Signature**	**Date**
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1. Administrative Information

1.1. LIST OF ABBREVIATIONS

Acronym	Definition
ADE	Adverse Device Event
AE	Adverse Event
CI	Confidence Interval
CIP	Clinical Investigation Plan
CRF	Case Report Form
eCRF	Electronic Case Report Form
EC	Ethics Committee
EDC	Electronic Data Capture
EQ-5D	A standardized health-related quality of life instrument by the EuroQuol Group
EU MDR	European Medical Device Regulation
FAAM	Foot and Ankle Ability Measure
FR	Final Report
FU	Follow-Up
ICF	Informed Consent Form
ICH-GCP	International Conference of Harmonisation Good Clinical Practice
IFU	Instructions for Use
ITT	Intent-to-Treat
Intra-Op	Intra-Operative
IR	Interim/Annual Report
IRB	Institutional Review Board
LTFU	Lost to Follow-Up
Op	Operative
PP	Per Protocol
Post-op	Post-Operative
Pre-Op	Pre-Operative
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
UADE	Unanticipated Adverse Device Effect

1.2. STATISTICAL ANALYSIS PLAN REVISION HISTORY

Version	Effective Date	Description	Reason
1	12 January 2022	Initial Version	n/a

1.3. ROLES AND RESPONSIBILITIES

Role	Contributor	Affiliation
Author/ Clinical Investigation Manager (CIM)	Jennifer Seidman	Stryker
(Senior) Statistician	Jovi Quiton	Stryker
Clinical Research Head (CRH)	Rebecca Gibson	Stryker

2. Introduction

2.1. BACKGROUND AND RATIONALE

The European Union (EU) Medical Device Regulation (MDR) 2017/83/EC applies to all medical device manufactures who intend to market their products in the EU. The EU MDR has increased the requirements for clinical data needed for products to maintain certification. Under the regulation, the manufacture must proactively collect and evaluate clinical data to establish and verify:
that under normal conditions of use, a device achieves the performance intended as specified by the manufacturer;

- the clinical benefits of a device as specified by the manufacturer;
- the clinical safety of the device;
    - Identify previously unknown side-effects;
    - Monitor the intended side-effects and contraindications;
    - Identify and analyze emerging risks on the basis of factual evidence;
- ensure the continued acceptability of the benefit / risk ratio; and
- systemic misuse or off-label use with a view to verify the intended purpose is correct.

Wright Medical is conducting this observational study to meet the clinical data requirements for the EU MDR.

The purpose of this post-market clinical observational study is to demonstrate the safety and performance of the Wright product after implantation over a standard follow-up period using patient reported outcome measures (PROMs) related to quality of life and functional improvements, safety of the implants, as well as radiographic assessments (X-Rays).

The outcome measures collected in this study will be analyzed and reported as required for local, regional, and country requirements (i.e., regulatory authorities and notified bodies).

2.2. CLINICAL INVESTIGATION DESIGN

This investigation is a global, multi-center, post-market observational study. The study planned to enroll 40 patients per device according to sample size calculations based on the EQ-5D (See study protocol). The enrollment period is expected to be 5 years. Based on the varied definitions of clinical lifetime for each device, the follow-up (FU) period will range 12 weeks to 10 years.

Data will be collected at baseline, surgery, at last scheduled standard of care and/or surgeon release FU time point. Additionally, PROMs and safety may be followed yearly to sufficiently assess the safety of the product over the clinical lifetime as needed based on the current risk analysis for the product.

3. Statistical Procedure

3.1. FRAMEWORK

The purpose of this statistical analysis plan is to guide the analysis and production of statistical output for the Wright Foot & Ankle Post-Market Observational Study. The company decided to discontinue enrollment to the study on November 1, 2021. At study end date, there were 122 patients enrolled in the study. The sample size of 40 patients per device that was originally planned in the study was therefore not met.

The study required at least 40 sample size for each Wright medical device (See INT19-MDR-001 Protocol. Version 3). For the same sample size parameters in the protocol n=10, will yield a power of 0.5. Thus, for the purpose of reporting statistically valid outcomes, descriptive summary statistics will be presented for Wright devices implanted in at least 10 patients enrolled in the study. Patient data on devices that has less than 10 implanted patients will be provided in the listings to be made available for future study or reference. Appendix Table 1 lists the Wright devices that are included in the study.

As the goal of the study is to determine the performance and safety of each device under investigation, analysis of outcomes will be done for each device the patient received. Note that a patient may have received more than one of the Wright devices. In all analysis of outcomes, patient level data will be included in the analysis for each device he/she received.

All analysis to be conducted are of descriptive nature only. No test of hypothesis will be performed. All quantitative variables, including those based on calculations (i.e., improvement from baseline), will be analyzed with a case summary evaluation before the detailed characteristics and parameter can be evaluated. A case summary contains a listing of the number of valid cases/values, missing cases/values (if any) and total cases/values in the specific analysis. The mean and median will be reported to assess the average or centrality of quantitative variables. Improvement from baseline in patient reported outcome (PROM) will be assessed at each post-surgery visit. Improvement will be based on the difference in raw scores.

Whenever the available data allows, the standard deviation, interquartile range (IQR) and maximum and minimum will be calculated. All quantitative variables will be assessed for normality via the Shapiro-Wilk test. The 95% confidence interval (CI) of the mean will be presented when the normality of the data is met.

All qualitative variables, including those based on summaries (secondary elements), will be analyzed listing the proportions, frequencies, column and row totals and missing proportion (if any).

The proportion of device surviving at each visit will be summarized for each device. Rates will be computed based on available data. Missing data will not be imputed.

No imputations for missing data will be conducted.

3.1.1. Primary Analysis / Endpoint

Improvements in subject quality of life after surgery will be assessed by constructing 95% confidence interval for the mean change from baseline score in EQ-5D-5L.

3.1.2. Secondary Analyses

FAAM score improvements from baseline will be summarized with 95% confidence interval for the mean.

Safety of Wright medical products will be assessed by the frequency and rates of the with collected AE safety profiles.

Surgeon and patient assessment of Wright devises will be presented descriptively.

3.1.3. Additional Analyses

Additional Analyses are outlined in the subsequent sections. Analysis details (variables, level of measurement, planned steps) are listed in-depth in the SAP.

- Fusion/Consolidation time for applicable devices
- Deformity Correction for applicable devices

4. Methods

4.1. RANDOMIZATION

No randomization was implemented in the study. A consecutive series of subjects at each site meeting all the eligibility criteria will be enrolled in this clinical investigation.

4.2. STATISTICAL INTERIM ANALYSES AND STOPPING GUIDANCE

Interim analyses will be performed on an annual basis. The progress of the clinical investigation will be reported together with the interim results on the variable level according to the analysis plan.

There will be no stopping rules specified for this clinical investigation.

4.3. TIMING OF FINAL ANALYSES

The full final report with complete analyses, progress and conduct reporting will be created at the end of this clinical investigation.

4.4. TIMING OF OUTCOME ASSESSMENT

Data will be collected at baseline, surgery, at last scheduled standard of care and/or surgeon release FU time point. Additionally, PROMs and safety may be followed yearly to sufficiently assess the product over the clinical lifetime as needed based on the current risk analysis for the product.

The follow-up evaluations will include assessment of device-related adverse events/incidents, evaluation per EQ-5D-5L and FAAM scores as well as surgeon surveys. See the section below for visit windows and a list of assessments to be performed at each visit, given by the CIP.

Table 4.4.1: Assessments and Clinical Investigation Elements

Procedures	**Pre-op/ Op**	**Final Clinical Follow-Up Visit** (Op to 1yr)	**1-10 yr** (-/+1 yr) (yearly as necessary) [4]	**Study Close**
Informed Consent	X			
Inclusion/Exclusion Criteria	X			
Medical History/Demographics	X			
Operative (Surgical) procedure/device	X			
EQ-5D	X	X	X	
FAAM	X	X	X	
Surgeon Survey with radiographic assessment		X		
Adverse Event Assessment	X	X	X[3]	
Patient Survey			X	
End of Study				X
Surgical Intervention[1]				
*Sponsor-approved Unscheduled Visit [2]				

[1]&[2] These are not scheduled time point events but will be observed throughout study participation

[3] Only required when patient survey indicates an adverse event occurred

[4] Follow-up time points only executed if needed per device clinical lifetime definition

4.5. STATISTICAL SOFTWARE

All statistical analyses will be performed using SAS Version 9.4 or higher on a SAS PC platform.

4.6. MISSING DATA

The intent is to collect as complete a dataset as possible. Nevertheless, in some situations missing data cannot be avoided. The reports and tables therefore will show the number and percentage of missing cases for each analyzed variable in relation to the enrolled cases for each post-operative assessment.
Missing data will be reported for each variable or calculation (if any) and overall totals will be reported including the proportion of missing data (if any).

4.7. UNITS

See analysis chapter for details related to units used for the different variables and calculations. In case of collection of variables with non-SI units (i.e., pounds instead to kilograms), conversion of such data into SI units (and vice versa) will be ensured and both results will be reported for the full set of available subjects next to each other in the interim/annual and/or final reports.

4.8. CALCULATIONS AND TRANSFORMATIONS

Distances between times and differences between score results will be calculated. For full details of variables used for calculations and the creation of new variables based on these calculations, see analysis chapter.

5. Population and Progress

All analysis will include all subjects implanted with any of the Wright devices listed in Appendix 1, hence called Treated population.

6. Analysis

This section will contain the instructions for data analysis and table templates of the presentation of statistical analysis results. The components of the table template will guide the statistical programming and report generation.

6.1. Patient Accounting

See Table 1.1. A summary of subject disposition will be made, noting the number who attended the baseline visit, had the surgery visit by Wright device implanted/used, and then subsequently attended the remaining study visits.

6.2. Baseline Characteristics

Subject eligibility

See Table 1.2. The inclusion and exclusion criteria will be summarized for the treated population in order to assess adherence or deviation of subjects to the study eligibility.

Demographic

See Table 1.3. Demographics and clinical characteristics at baseline will be summarized descriptively, and will include the following: Age, Race; Gender; Height in cm; Weight in kg, BMI (kg/m^2) and smoking status. Age in years will be calculated as:

```
age = FLOOR((INTCK('month',BRTHDT,INFCONDT) - (day(INFCONDT) < day(BRTHDT))) / 12);
```

Medical Conditions

See Table 1.4. The pre-operative relevant medical conditions will be summarized by frequency and proportion for each Wright device.

6.3. Protocol Deviations

See Table 1.5. Deviations from the protocol that occurred during the conduct recorded for each patient will be summarized by frequency and rate of occurrence.

6.4. Intra-operative Factors

See Table 2.1. The operative information will be summarized descriptively and will include the following: indication for use, prior surgery, location of surgery.

6.5. Effectiveness

6.5.1. Primary endpoint analysis: EQ-5D

See Table 3.1. EQ-5D is the primary endpoint of the study. EQ-5D is generic health survey that can be used to compare improvement across different interventions and measure changes in health-related quality of life over time. Three language versions of the EQ-5D questionnaire: English, German and France were used. The scores regardless of language will be combined in the analysis. The EQQ-5D Two components of the EQ-5D will be summarized: Index value and overall health score. The five (5) health state measure in the EQ-5D questionnaire will be used to calculate the EQ-5D index value. An EQ-5D for patient standardized for the country origin will be computed based on the total score of the health measures. The country-specific EQ-5D reference scores will be obtained from EuroQoL Group (www.euroqol.org). A high EQ-5D index value indicates a better health state while a low EQ-5D index value indicates a wore health state. On the other hand, the Eq-5D overall health score, ranges from 0 to 100, is a single measure of the patient's assessment of their current health status. Higher score indicates better health state while a low score indicates a worse health state.

6.6.2 Secondary endpoints

FAAMS

See Table 3.2.1 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. Like the EQ-5D, three language versions of the FAAM questionnaire were used. The FAAM consists of 29-item questions divided into two subscales: 21-item activities of daily living (ADL) subscale, 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 score on each of the items are added together to get the subscale total score. The ADL subscale total score range from 0 to 84 and 0 to 32 for the sports subscale. The patient score for the ADL and sports subscale will be transformed to percentage scores by considering the highest possible score for non-missing items. Higher score indicates hinger level of function for each subscale, with 100% representing no dysfunction (Martin et al., 2009).

See Table 3.2.2 Patients assessed their current level of function as Normal, Nearly Normal, Abnormal, or Severely Abnormal. Summaries will be presented for each Wright device and visit.

SURGEON ASSESSMENT AND RADIOGRAPHIC OUTCOME

See Table 4.1. At the final visit of the patient, the attending surgeon assessed the surgical foot to assess the outcome. The surgeon also assessed the radiographic outcome of the surgery. For each Wright device of interest, the following will be summarized:

- Days from surgery to radiographic evaluation
- Imaging procedure done: standing AP/lateral, hindfoot alignment view, CT, MRI, Other
- Surgeon opinion on Wright product performance
- Bony union outcome for joint arthrodesis device

See Table 4.2. The surgeon assessment of angle deformity correction based on radiograph will be summarized for the following:

- Angle deformity correction for hallux valgus deformity: Halux Valgus angle, Intermetatarsal angle, Distal Metatarsal Articular Angle
- Angle deformity correction for flatfoot or charcot: Mearys angle, Talonavicular Angle, Other
- Surgeon observed adverse event (Y/N)

6.6. HARMS AND SAFETY

See Table 5.1. The safety of each device will be summarized in the interim and final report. Overall summary of adverse events will be presented for each device. Total frequencies and percentages of adverse events for each Wright device will be summarized for the following factors:

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

The occurrence and rate of SAE will be further categorized by the outcome of the SAE (i.e., death, hospitalization).

The rates for device failure will be the basis of the survival rates for each device. The above AE factors will also be summarized for each study site.

7. Listings

Appendix II contains the contents of Listing of Tables (Appendix 2A), Listings (Appendix 2C and Figures (Appendix 2D). All patient data listings will include page-breaks at the beginning of each investigative site to allow simple partitioning of the listing data by site.

All listings will contain the following standard elements: study name and protocol number, title of display, data version date, and data analysis date.

8. Appendices

8.1. Appendix 1. List of Wright medical devices included in the study.

Device	Follow-Up Time Period
611 Nail	1 year
BIOARCH	1 year, 2 year
BIOFOAM Ankle Spacers	1 year
BIOFOAM Wedge System	1 year
CHARLOTTE MUC Screws	1 year
CHARLOTTE Quick Staple	1 year
CHARLOTTE Snap-Off Screws	1 year
CLAW II	1 year
DARCO Headed Screws	1 year
DARCO Headless Screws	1 year
DARCO MFS	1 year
DARCO MRS	1 year
DARCO Plantar Lapidus Plate	1 year
DART-FIRE	1 year
FUSEFORCE	1 year
FUTURA CSI	1 year, 2 year
G-FORCE	1 year, 2 year
GRAVITY SYNCHFIX	1 year, 2 year
HV Screws	1 year
MaxLock Edgelock Plate	1 year
MiniMaxLock ISO Plate	1 year
MICA Screws	1 year
NEXFIX Snap-Off Screws	1 year
Omni Evolution Screws	1 year
ORTHOLOC 2 Ankle Fracture	1 year
ORTHOLOC 2 CROSSCHECK	1 year
ORTHOLOC 2 Small Bones	1 year
ORTHOLOC 3Di Ankle Fusion	1 year
ORTHOLOC 3Di Hallux	1 year
ORTHOLOC 3Di Midfoot/Flatfoot	1 year
ORTHOLOC Forefoot Fracture	1 year
ORTHOLOC Plantar Lapidus	1 year
ORTHOLOC Calc Fracture	1 year
PHALINX	1 year
PITON	1 year
PRO-TOE VO	1 year
SALVATION ExFix	1 year
SALVATION Bolts and Beams	1 year
SALVATION 3Di Plates	1 year
SWANSON Toes	1 year, 2 year, 3 year, 4 year, 5 year, 6 year, 7 year, 8 year, 9 year, 10 year
Telya	1 year
UNIMA EVO and NEUTRA Screws	1 year
VALOR Nail	1 year

8.2. Appendix 2 – Listing of Tables and Listings, Table Templates

A. LISTING OF TABLES

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Table	5.2	Life table for device failure by device
Table	5.3	Life table for time to death by device
Table	6.1	Adverse event by device

B. ANALYSIS TABLE TEMPLATES

Table 1.1. Patient Accounting.

	Site		
	Baseline	**Post Op Visit 1**	**Post Op Visit 2**
Device 1			
Total	xx	xx	xx
Completers	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Reason for discontinuation			
Lost to follow-up	xx	xx	xx
Withdrew consent	xx	xx	xx
Adverse event	xx	xx	xx
Other	xx	xx	xx
:	:	:	:
Device k			
Total	xx	xx	xx
Completers	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Reason for discontinuation			
Lost to follow-up	xx	xx	xx
Withdrew consent	xx	xx	xx
Adverse event	xx	xx	xx
Other	xx	xx	xx

Table 1.2. Subject Eligibility

	Inclusion Quiestions			**Exclusion Questins**			Eligible
	1	2	3	1	2	3	
	f(%)	f(%)	f(%)	f(%)	f(%)	f(%)	f(%)
All Sites	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)
Site							
1	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)
2	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)
3	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)
4	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)	xx(xx.xx)
Total							xx

Table 1.3. Demographics and Clinical Characteristics

Factors	Freq (%)						
Gender							
Male	xx(xx.x%)						
Female	xx(xx.x%)						
Smoking							
Never	xx(xx.x%)						
Previous							
Current, ≤1 pack/day	xx(xx.x%)						
Current, >1 pack/day							
	n	**mean**	**sd**	**min**	**max**	**median (IQR)**	**95% CI**
Age (years)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x(xx.x, xx.x)	(xx.x, xx.x)
Weight (kg)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x(xx.x, xx.x)	(xx.x, xx.x)
Height (cm)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x(xx.x, xx.x)	(xx.x, xx.x)
BMI (kg/m2)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x(xx.x, xx.x)	(xx.x, xx.x)

Table 1.4. Medical History

Factors	Freq (%)
Autoimmune Disorder	
Cardiovascular Disorder	xx(xx.x%)
Respiratory Disorder Skin	xx(xx.x%)
Gastrointestinal Disorder	
Genitourinary Disorder	xx(xx.x%)
Hematological Disorder	xx(xx.x%)
Psychological Disorder	xx(xx.x%)
Musculoskeletal Disorder	xx(xx.x%)
Neurological Disorder	xx(xx.x%)
Endocrine/Metabolic Disorder	xx(xx.x%)
Subcutaneous Tissue Disorder	xx(xx.x%)
Peripheral Vascular Disease	xx(xx.x%)
Diabetes	xx(xx.x%)
Type I	xx(xx.x%)
Type II	xx(xx.x%)
Other	xx(xx.x%)

Table 1.5. All Protocol Deviations

Subjects	Type of Deviation				Total Deviations
	Dev 1	Dev 2	Dev 3	Dev 4	
	Freq (%)	Freq (%)	Freq (%)	Freq (%)	
All Subjects (N=xx)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
Wright Device	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
Device 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
Device 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx
:					
Device k	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx

Note:
Dev 1 -Visit completed but outside of window
Dev 2-Completely missed follow up visit
Dev 3 -Patient questionnaire(s) not done
Dev 4-Other deviations

Table 2.1. Surgical and Operative Information

Factors	Device 1	Device 2	...	Device k
	Freq (%)	Freq (%)		Freq (%)
Indication for use				
Post traumatic	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Arthritis	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Fracture	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Fusion	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Reconstruction/Correction	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Revision procedure	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Instability	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Skeletal defect after tumor selection	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Prior surgery				
Yes	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
No	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Location of Surgery				
Right	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)
Left	xx(xx.x%)	xx(xx.x%)		xx(xx.x%)

Table 3.1 EQ-5D by device and visit

Wright Device	Visit		
	Baseline (n=xx)	Post-op Visit 1 (n=xx)	Post-op Visit 2 (n=xx)
Device 1			
Overall Health			
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Index Value	xx.x	xx.x	xx.x
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Change from Baseline			
Overall Health			
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)
Index Value		xx.x	xx.x
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)
Device 2			
Overall Health			
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Index Value	xx.x	xx.x	xx.x
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Change from Baseline			
Overall Health			
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)
Index Value		xx.x	xx.x
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)
:			

Device k			
Overall Health			
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Index Value	xx.x	xx.x	xx.x
mean±sd	xx.x±xx.x	xx.x±xx.x	xx.x±xx.x
median	xx.x	xx.x	xx.x
min,max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Change from Baseline			
Overall Health			
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)
Index Value		xx.x	xx.x
mean±sd		xx.x±xx.x	xx.x±xx.x
median		xx.x	xx.x
min,max		xx.x, xx.x	xx.x, xx.x
95% CI		(xx.x, xx.x)	(xx.x, xx.x)

Table 3.2.1 FAAM score by device and visit.

Wright device		Baseline				Follow-up Visit				Final Visit			
		n	mean±sd	min,max	95% CI	n	mean±sd	min,max	95% CI	n	mean±sd	min,max	95% CI
Device 1													
	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.x)
	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.x)
	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.x)
	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.x)
	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)
	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)
Device 2													
	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.x)
	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.x)
	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.x)
	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.x)
	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)
	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)
:													
Device k													
	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.x)
	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.x)
	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.x)
	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.x)
	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)
	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)

Note:
ADL - activities of daily living
SANE - single assessment numeric evaluation

Tale 3.2.2 FAAM overall rating by device and visit

Wright device	Baseline			
	Normal	**Nearly Normal**	**Abnormal**	**Severely abnormal**
Device 1	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Device 1	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
:				
Device k	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
	Final Visit			
	Normal	**Nearly Normal**	**Abnormal**	**Severely abnormal**
Device 1	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
Device 1	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)
:				
Device k	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)

Table 4.1 Surgeon evaluation by device

Wright device	Follow-up Visit			Final Visit		
	Factors	N	%	Factors	N	%
Device 1	**Bony union**			**Bony union**		
	Yes	xx	xx.x%	*Yes*	xx	xx.x%
	No	xx	xx.x%	*No*	xx	xx.x%
				Wright product performed as intended		
				Yes	xx	xx.x%
				No	xx	xx.x%
Device 2						
	Bony union			**Bony union**		
	Yes	xx	xx.x%	*Yes*	xx	xx.x%
	No	xx	xx.x%	*No*	xx	xx.x%
				Wright product performed as intended		
				Yes	xx	xx.x%
				No	xx	xx.x%
:						
Device k						
	Bony union			**Bony union**		
	Yes	xx	xx.x%	*Yes*	xx	xx.x%
	No	xx	xx.x%	*No*	xx	xx.x%
	No	xx	xx.x%	*Other*	xx	xx.x%
				Wright product performed as intended		
				Yes	xx	xx.x%
				No	xx	xx.x%

Table 4.2 Surgeon assessment of deformity correction based on radiograph by device.

Wright device		Baseline						Final visit						Improvement					
		n	mean	sd	min	max	95% CI	n	mean	sd	min	max	95% CI	n	mean	sd	min	max	95% CI
Device 1																			
	Degree of deformity correction																		
	Hallux valgus procedure																		
	Hallux valgus	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Intermetatarsal Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	DMA Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Flatfoot or charcot procedure																		
	Mearys Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	TNV Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Other	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
Device 2																			
	Degree of deformity correction																		
	Hallux valgus procedure																		
	Hallux valgus	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Intermetatarsal Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	DMA Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Flatfoot or charcot procedure																		
	Mearys Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	TNV Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Other	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
:																			
Device k																			
	Degree of deformity correction																		
	Hallux valgus procedure																		
	Hallux valgus	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Intermetatarsal Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	DMA Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Flatfoot or charcot procedure																		
	Mearys Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	TNV Angle	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)
	Other	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)	xx.x	xx.x	xx.x	xx.x	xx.x	(xx.x, xx.x)

Table 5.1 Adverse Events by device.

Adverse Events	**Device 1**		**…**		**Device *k***	
	Subjects (%)	**Events**	**Subjects (%)**	**Events**	**Subjects (%)**	**Events**
Procedure-Related	xx (xx.x%)	xx			xx (xx.x%)	xx
Device-Related	xx (xx.x%)	xx			xx (xx.x%)	xx
Device Failure	xx (xx.x%)	xx			xx (xx.x%)	xx
Unanticipated AE	xx (xx.x%)	xx			xx (xx.x%)	xx
Serious AE	xx (xx.x%)	xx			xx (xx.x%)	xx
Hospitalization	xx (xx.x%)	xx			xx (xx.x%)	xx
Death	xx (xx.x%)	xx			xx (xx.x%)	xx
Required Treatment	xx (xx.x%)	xx			xx (xx.x%)	xx
Physical Therapy	xx (xx.x%)	xx			xx (xx.x%)	xx
Medication	xx (xx.x%)	xx			xx (xx.x%)	xx
Surgery	xx (xx.x%)	xx			xx (xx.x%)	xx
Other	xx (xx.x%)	xx			xx (xx.x%)	xx

C. LISTING OF LISTINGS

Listing 1 Demographic Information
Listing 2 Inclusion/Exclusion Criteria
Listing 3 Protocol Deviations
Listing 4 Medical History
Listing 5 Surgical and Operative Information
Listing 6 EQ-5D Score
Listing 7 FAAMS Score
Listing 8 Surgeon assessment and radiographic deformity correction assessment
Listing 9 Adverse Events
Listing 10 Study Completion

9. References

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.

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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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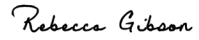
Rebecca Gibson rebecca.gibson@stryker.com Director, Clinical Operations Stryker Corporation - Trauma & Extremitites Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: B69B71B0-C1FA-437D-B216-59BFBEB69FE2 Using IP Address: 174.247.29.182 Signed using mobile With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/12/2022 9:16:38 AM Viewed: 1/12/2022 9:30:08 AM Signed: 1/12/2022 9:30:39 AM
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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	1/12/2022 6:44:47 AM
Certified Delivered	Security Checked	1/12/2022 9:30:08 AM
Signing Complete	Security Checked	1/12/2022 9:30:39 AM
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Required hardware and software

Operating Systems:	Windows2000? or WindowsXP?
Browsers (for SENDERS):	Internet Explorer 6.0? or above
Browsers (for SIGNERS):	Internet Explorer 6.0?, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	•Allow per session cookies •Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

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