STATISTICAL ANALYSIS PLAN

INFINITY™ Total Ankle Replacement Follow-up (ITAR)

Protocol Number: US17-TAR-001

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Abbreviations

AE	Adverse Event
AOS	Ankle Osteoarthritis Score
BMI	Body Mass Index
CFR	Code of Federal Regulations
CDRH	Center for Device Radiological Health
CI	Confidence Interval
COFAS	Canadian Orthopaedic Foot & Ankle Society
CRF	Case Report Form
GCP	Good Clinical Practice
FAOS	Foot and Ankle Outcome Score
ICH	International Conference on Harmonization
IRB/ERC/REC	Institutional Review Board, Ethical Review Committee, Research Ethical Committee
LB	Lower Bound
MedDRA	Medical Dictionary for Regulatory Activities
PROMS	Patient Reported Outcome Measures
PROMIS	Patient Reported Outcome Measurement Information System
QoL	Quality of Life
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reactions
TAR	Total Ankle Replacement
UB	Upper Bound
Vs	Versus
WHO	World Health Organization

PROTOCOL SYNOPSIS

Study Title	The INFINITY™ Total Ankle Replacement Follow-up (ITAR)
Study Design	Prospective, multi-site, multi-year post-market clinical follow-up study
Study Group	Primary/Unilateral and/or bilateral Total Ankle Arthroplasty subjects implanted with INFINITY™ Total Ankle System
N Subjects	155 patients in 9 sites
Follow-Up Schedule	Subject enrollment will consist of a Pre-operative, Operative, 6 months, 1 yr., 2 yr., 5yr., 7 yr., 10 yr., and an unscheduled visit as needed.
Primary Objective	Evaluate the long-term survivorship of the INFINITY™ implant over 10 years
Secondary Objective(s)	Secondary objectives assessed will be to: • Identify and assess the implant for component loosening and/or subsidence, any osteolysis and/or cyst formation through radiographic evaluation early and throughout the lifetime of the implant. • Compare the improvements in self-reported physical, mental, and social health measures from pre-op through 10 years post operatively; assessed by PROMIS® Global Health. • Compare pain and functional improvement in the Ankle Osteoarthritis Score (AOS), which is a visual analogue scale specifically designed as a modification of the Foot Function Index. • Compare the improvement in patient/physician reported function scores from pre-op through 10 years post-operatively, assessed by the FAOS questionnaire. • Compare satisfaction of total ankle replacement post operatively utilizing a four-point scale • Identify and report the safety of the implant in terms of complications and adverse events.
Inclusion Criteria	Subjects to be included in the study must meet all of the following criteria: • Be 21 years of age or older at the time of surgery; • Diagnosed with unilateral and/or bilateral ankle joint disease; • Diagnosed with ankle joint damage from rheumatoid arthritis, post-traumatic, or degenerative arthritis; • Willing and able to consent to participate (written, informed consent; • Willing and able to attend the requested follow-up visits; • A clinical decision has been made to use INFINITY™ Total Ankle
Exclusion Criteria	Subjects will be excluded from the study if they meet any of the following criteria: • Subjects with an ankle condition, as determined by the investigator, to be an inappropriate candidate for a total ankle replacement;

INTRODUCTION

This statistical analysis plan is developed to guide the implementation of applicable statistical analysis and production of statistical output of US17-TAR-001 study. US-17-TAR-001 is prospective, multisite, multiyear post-market clinical study developed to evaluate the long-term survivorship of INFINITY® Total Ankle System implant over 10 years in the US. The study also seeks to assess the safety and possible complications with the implant and determine improvements in function and quality of life of patients. The study enrolled at least of 155 subjects.

The INFINITY® Total Ankle System is indicated in patients with ankle joints damaged by severe rheumatoid, post- traumatic, or degenerative arthritis, as well as for patients with a failed previous ankle surgery. Its intended use is to give patients limited mobility by reducing pain, restoring alignment and replacing the flexion and extension in the ankle joint.

The technological features of the INFINITY® Total Ankle System are similar to the predicate devices (INBONE® Total Ankle System, DePuy Agility™, INBONE® II Total Ankle System), which have all been cleared through the 510K process with the FDA, with regard to design and materials. The goal of the design was to limit the amount of bone resection and soft tissue dissection required for ankle arthroplasty; hence the overall profile of the INFINITY® Total Ankle System was significantly reduced along with the incision length required to perform the surgical procedure.

STUDY RATIONALE

The primary outcome measure of this post-market clinical observational study is to assess the survivorship of INFINITY™ Total Ankle System at 10 years. The secondary outcome measures are to characterize the improvements after implantation over a 10-year period using patient reported outcome measures related to quality of life, pain and functional improvements, and safety of the implant.

STUDY OBJECTIVES

This study aims to evaluate the long-term safety and survivorship of the INFINITY® implant over 10 years.

Effectiveness objectives

The primary effectiveness objective is to evaluate the long-term survivorship of the INFINITY® implant and improvement in patient function and quality of life. Survivorship will be measured by the length of time until implant failure.

Improvement in subject function and quality of life was assessed using the PROMIS Global Health, Ankle Osteoarthritis Score (AOS) and FAOS Questionnaire.

In addition, the level of patient satisfaction of their total ankle replacement was assessed at each post-operative visit.

Safety objectives

The safety objectives were to determine the long-term safety of the INFINITY® implant with respect to the patient experience of adverse events and complications associated with the implant such as component loosening and/or subsidence, any osteolysis and/or cyst formation through radiographic evaluation.

Part numbers and brief descriptions of configurations

The INFINITY® configurations and sizes that were included in the study are listed in the table below. These products are manufactured according to ICH GCP in accordance with applicable Good Manufacturing Practice (GMP) and with the ISO 14155:2011: through relevant manufacturing and related validation processes.

Table 1. List of **INFINITY®** and **INBONE®** configurations included in the study.

Part No.	**Description**	**Part No.**	**Description**
INFINITY® Poly Insert		**INFINITY® Tibial Component**	
33651106	POLY INSERT, SZ1/1+ 6MM	33650001	Tibial tray SZ1 STD
33651108	POLY INSERT, SZ1/1+	33650002	Tibial tray SZ2 STD
33651110	POLY INSERT, SZ1/1+	33650003	Tibial tray SZ3 STD
33651112	POLY INSERT, SZ1/1+	33650004	Tibial tray SZ4 STD
33652206	POLY INSERT, SZ2 6MM	33650005	Tibial tray SZ5 STD
33652208	POLY INSERT, SZ2 8MM	33650013	Tibial tray SZ3

33652210	POLY INSERT, SZ2 10MM	33650014	Tibial tray SZ4
33652212	POLY INSERT, SZ2 12MM	33650015	Tibial tray SZ5
33653206	POLY INSERT, SZ2 +6MM	**INFINITY® Talar Component**	
33653208	POLY INSERT, SZ2	33630021	Talar Dome SZ 1
33653210	POLY INSERT, SZ2	33630022	Talar Dome SZ 2
33653212	POLY INSERT, SZ2 +12MM	33630023	Talar Dome SZ 3
33653306	POLY INSERT, SZ3 6MM	33630024	Talar Dome SZ 4
33653308	POLY INSERT, SZ3 8MM	33630025	Talar Dome SZ 5
33653310	POLY INSERT, SZ3 10MM	**INBONE® II Talar Component &**	
33653312	POLY INSERT, SZ3 12MM	220220901	Talar Dome SZ 1
33654307	POLY INSERT, SZ3 + 7MM	220220902	Talar Dome SZ 2
33654309	POLY INSERT, SZ3 + 9MM	220220903	Talar Dome SZ 3
33654311	POLY INSERT, SZ3 11MM	220220904	Talar Dome SZ 4
33654313	POLY INSERT, SZ3 13MM	220220905	Talar Dome SZ 5
33654406	POLY INSERT, SZ4 6MM	200347901	Talar Stem 10 mm
33654408	POLY INSERT, SZ4 8MM	200347902	Talar Stem 14 mm
33654410	POLY INSERT, SZ4 10MM		
33654412	POLY INSERT, SZ4 12MM		
33655407	POLY INSERT, SZ4 +7MM		
33655409	POLY INSERT, SZ4 +9MM		
33655411	POLY INSERT, SZ4 +11MM		
33655413	POLY INSERT, SZ4 +13MM		
33655506	POLY INSERT, SZ5 6MM		
33655508	POLY INSERT, SZ5 8MM		
33655510	POLY INSERT, SZ5 10MM		
33655512	POLY INSERT, SZ5 12MM		

STUDY DESIGN

Overview

This study is a prospective, multi-site, multi-year post-market, follow-up clinical trial to evaluate the long-term survivorship of the INFINITY® Total Ankle System in the treatment of ankle joint damaged caused by severe rheumatoid, post- traumatic, or degenerative arthritis, as well as for patients with a failed previous ankle surgery. Prior to surgery, medical history, demographic, radiographic parameters and disease severity by COFAS type, varus/valgus deformity and function and quality of life of patients were collected.

At Day 0 (Surgery Day), information related to the subject's operation will be collected and recorded according to the Operative Information Case Report Forms, which included the following: Primary diagnosis, any previous surgery to index joint, date of operation, site location, surgical approach, instrumentation type (standard) or (additional approved INFINITY® instrumentation), concomitant operative procedures, cement use, intraoperative complications, and product description and eight-digit product code for all components implanted. Subjects were to return for clinical, functional and radiographic evaluations and safety evaluations at 6 months, 1 year, 2 years, 5 years, 7 years and 10 years post-surgery. The study planned to enroll 200 or more subjects in the US with 10 investigational sites, however, 155 patients participated when enrollment was closed. The study subjects included are those with ankle joints damaged by severe rheumatoid arthritis, post-traumatic disease, and degenerative arthritis and implanted with the INFINITY® Total Ankle System.

Inclusion/Exclusion Criteria

Subjects who met the following inclusion/exclusion criteria were voluntarily recruited by participating investigators:

Inclusion Criteria*:*

Subjects to be included in the study must meet all of the following criteria:

• Be 21 years of age or older at the time of surgery;

• Diagnosed with unilateral and/or bilateral ankle joint disease;

• Diagnosed with ankle joint damage from rheumatoid arthritis, post-traumatic, or

degenerative arthritis;

• Willing and able to consent to participate (written, informed consent;

• Willing and able to attend the requested follow-up visits;

• A clinical decision has been made to use INFINITY™ Total Ankle System replacement prior to enrollment in the research.

Exclusion Criteria*:*

Subjects will be excluded from the study if they meet any of the following criteria:

• Subjects with an ankle condition, as determined by the investigator, to be an inappropriate candidate for a total ankle replacement;

• Subjects requiring revision total ankle replacement of the ankle being considered for study.

Table 2. Study schedule.

Procedures	**Pre-op**	**Op.**	**6 mo +/-30 days**	**1 yr +/-60 days**	**2 yr +/-60 days**	**5 yr +/-60 days**	**7 yr +/-60 days**	**10 yr +/-60 days**	**Study Close**
Informed Consent	X								
Inclusion/Exclusion Criteria	X								
Medical History & Demographics	X								
Operative Surgical procedure/device		X							
PROMIS Global Health	X		X	X	X	X	X	X	
Ankle Osteoarthritis Score (AOS)	X		X	X	X	X	X	X	
FAOS Questionnaire	X		X	X	X	X	X	X	
Total Ankle Replacement			X	X	X	X	X	X	
Radiographic Assessment	X		X	X	X	X	X	X	
Adverse Event Assessment		X	X	X	X	X	X	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 for throughout study participation.

STATISTICAL METHODS

General Considerations

All enrolled subjects who underwent total ankle replacement implanted with INFINITY™ or INBONE® product configurations listed in Table 1 will be included in the analysis. All data will be summarized for all subjects at baseline and at every post-surgery visit, namely at 6 months, 1, 2, 5, 7, and 10 year post surgery.

Categorical data will be displayed as frequency and percent, and continuous data will be displayed using descriptive statistics (N, mean, standard deviation, quartiles, minimum and maximum, CI). Subgroup analyses will be conducted for all the patient reported outcomes: PROMIS Global Health AOS and FAOS. Subgroup analysis and comparisons will be presented for the following factors:

- surgical instrumentation type (standard vs additional approved instrumentation),
- type of primary disease diagnosis (Rheumatoid arthritis, Post traumatic, Degenerative);
- COFAS type (Types 1-4);
- Varus and/or valgus degree of deformity
- Radiographic radiolucency.

Radiolucency factors will be categorized independently with respect to linear and cystic radiolucency as follows:

Linear radiolucency:	Group 1: Present Linear radiolucency (>2mm)
	Group 2: Absent Linear radiolucency (>2mm)
Cystic radiolucency:	Group 1: Present Cystic radiolucency (>5mm)
	Group 2: Absent Cystic radiolucency (>5mm)

Subgroup analysis of the patient satisfaction of their total ankle replacement post operatively will only be done for surgical instrumentation type.

Pre- and Post- Surgery Tests

The PROM scores at each post-surgery visit will be compared with the baseline score via a t-test for two related samples or via the nonparametric Wilcoxon Rank Sum test for nonnormally distributed scores.

Group Comparisons

At each post-surgery visit, the patient reported outcome (PROMIS, AOS and FAOS) score and the change from baseline scores will be analyzed. Analysis of covariance (ANCOVA) with baseline score as a covariate factor will be implemented for all comparisons (i.e., comparison by disease diagnosis). The components of the ANCOVA model are: baseline scores, subgroups or independent factor and subgroup-by-baseline interaction.

Adjusted mean of subgroups with 95% confidence intervals will be presented. Bonferroni pairwise adjusted comparison of means will be done when significant differences among the group is established.

All statistical analysis tables for PROMIS, AOS and FAOS will be will have the elements as presented in the template below.

Table 3. Template of statistical tables for PROMIS, AOS and FAOS

Visit	Factor (or sub-factor X)	All Subjects (N=xx)	Group 1 (N=xx)	Group 2 (N=xx)
Pre-operative	N	xx	xx	xx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x
	1st Q, Median, 3rd Q	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
	Min, Max	xx.x , xx.x	xx.x , xx.x	xx.x , xx.x
	Difference in means			xx.x
	p-value for mean difference*=0			x.xxx
Post-op Visit	N	xx	xx	xx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x
	1st Q, Median, 3rd Q	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
	Min, Max	xx.x , xx.x	xx.x , xx.x	xx.x , xx.x
	p-value for change from baseline***	x.xxx	x.xxx	x.xxx
	Difference in group means			xx.x
	p-value for group difference**=0			x.xxx
	Adjusted mean ± se**		xx.x ± xx.x	xx.x ± xx.x
	95% CI for the Difference in Mean**			(xx.x , xx.x)
	Change from Baseline			
	N	xx	xx	xx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x
	1st Q, Median, 3rd Q	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
	Min, Max	xx.x , xx.x	xx.x , xx.x	xx.x , xx.x
	Difference in group means			xx.x
	Adjusted mean ± se**		xx.x ± xx.x	xx.x ± xx.x
	95% CI for the Difference in Mean**			(xx.x , xx.x)
	p-value for group mean difference=0**			x.xxx

Note: Results will be presented for each post-operative visit.
*One-way analysis of variance for group difference.
**Results of ANCOVA, group variable as fixed effect and baseline as covariate, means adjusted for baseline.
***t-test or Wilcoxon test p-value for two related samples.

Test of assumptions

The normality assumption of ANCOVA will be assessed through the Shapiro-Wilk test. Another important assumption of ANCOVA is that the relationship between the dependent factor and the covariate for each subgroup are the same. The regression slope of response factor on the covariate at each subgroup will be tested for equality. The Levene's test will be implemented to test the assumption of homogeneity of regression slope of response factor on the covariate at each subgroup.

Patient Disposition and Accounting

A table to account for the status of all enrolled subjects will be constructed to include frequency of subject non-completion, subject retention rates and deaths at the 10+ years follow-up period. The reasons for subject non-completion and causes of death will also be summarized.
The accounting table will also include, at each follow-up time, the number of subjects followed-up who have complete data and the number of subjects who have any data.

The patient disposition summaries discussed above will also be presented for patients implanted per the "standard instrumentation" and for patients implanted per the "approved additional instrumentation".

Demographics and Baseline Clinical Characteristics

Demographics and clinical data including gender, age, race, height, weight, BMI, smoking status, affected foot or ankle, foot or ankle to be treated, will be summarized with descriptive statistics (min, max, mean, median, and standard deviation).

Subject's pre-operative end-stage arthritis radiograph results will be summarized based on the Canadian Orthopaedic Foot and Ankle Society (COFAS) categories as follows:

Type 1: Isolated ankle arthritis

Type 2: Ankle arthritis with intra-articular varus or valgus deformity or a tight heel cord, or both

- intra-articular ankle varus or valgus alignment was defined as the angle of the proximal talar surface (talar tilt) to the lateral border of the tibia in the distal diaphysis and metaphyseal region more than 10 degrees on the AP weightbearing ankle views

Type 3: Ankle arthritis with hindfoot deformity, tibial malunion, midfoot abductus or adductus, supinated midfoot, plantar flexed first ray, etc.

- hindfoot deformity defined as the angle between the lateral border of the calcaneus

and the long axis of the tibia on the AP view of the ankle (varus more than 5 degrees, valgus more than 10 degrees)

- Tibial deformity defined as an angulation between the lateral border of the tibia more than 10 degrees on the AP view of the ankle, or
- patient has required staged surgical deformity as part of the management of the ankle arthritis (within 18 months of TAR), this should be considered a type 3

Type 4: Types 1, 2, and 3 plus subtalar, calcaneocuboid, or talonavicular arthritis

The post-operative radiographic evaluations are done to report migration, loosening, subsidence of the device, any osteolysis and cyst formation.

Survivorship of INFINITY® Total Ankle System

Survivorship of INFINITY® Total Ankle System will be based on secondary surgical intervention performed on the original implant. The Kaplan Meier survivorship method and life table analysis will be employed. Time to surgical intervention due to implant failure will be the survivorship endpoint of INFINITY® Total Ankle System. In addition, time to reoperation to exchange or remove any part of the INFINITY® Total Ankle System or surgical intervention due to failure of the implant as survivorship endpoint will also be analyzed. Subjects who did not undergo revision or reoperation due to implant failure at the time of reporting will be censored at the last follow-up. The Kaplan Meier survival curve with the 95% Confidence Interval will be constructed.

Table . Kaplan-Meier life-table survival of INFINITY® Total Ankle System.

Year since implantation	Number at start	Number of failed implant	Lost	Survival Rate	95% Confidence Interval
0-1					
1-2					
2-3					
3-4					
4-5					
5-6					
6-7					
7-8					
8-9					
9-10					

Patient Reported Outcome Measures (PROMS)

Three PROMS: PROMIS, FAOS and AOS are measured prior to surgery and at very post-surgery visit. Descriptive summaries and confidence intervals at each visit will be presented. In addition, improvement from baseline in PROMS score will also be presented descriptively.

PROMIS Global Health

The Patient-Reported Outcomes Measurement Information System (PROMIS®) is a National Institutes of Health initiative to develop state-of-the-science measures that assess function and well-being in the physical, mental and social domains of health. PROMIS® have two components: physical and mental health. Scoring the PROMIS will be based on the PROMIS Global Health Scoring guidance (PROMIS® Global Health Scoring Manual).

Foot and Ankle Outcome Score (FAOS)

FAOS is a self-report measure that evaluates symptoms and functional limitations in individuals with generalized foot and ankle disorders. Items for the FAOS were adapted from the Knee Injury and Osteoarthritis Outcome Score. The FAOS is composed of the

following 5 subscales: pain (9 items), other symptoms (7 items), activities of daily living (7 items), sports and recreational activities (5 items), and foot and ankle-related quality of life (4 items). Each of the FAOS subscale are standardized so that score ranges from 0 to 100, where 100 indicates no problems and 0 indicates extreme problems.

Ankle Osteoarthritis Score (AOS)

The AOS consist of 2 components: Pain and Disability, with 9 questions each, are used to calculate the Total AOS score. The score is from zero to one hundred with a lower score indicating more normal function

Radiographic Assessment

Pre-operative radiograph assessment will be summarized based on the COFAS scale and by the degree of varus and/or valgus deformity. Post-operatively, at 6 months, one, two, five, seven, and ten years follow-up visits, radiographic findings implant component migration, loosening, subsidence and issues of osteolysis, cyst and other relevant radiographic findings will be summarized as rates and frequencies for all subjects and by subgroups. At the end of the study, the overall rates of these radiographic findings will also be summarized.

TAR Satisfaction

At each post-operative visit, the patient satisfaction of their total ankle replacement will be summarized by frequency and percent for each satisfaction category. Rates will be calculated based on the number of patients reporting.

Planned visits and Follow-Up Time Points

Subjects will be seen prospectively at the following intervals Pre-Op, Operative, 6 months, 1, 2, 5, 7, and 10 years. There are special circumstances where subjects required a visit outside the windows of the established visits, data collected from unscheduled visits will be included and analyzed. Data from an unscheduled visit maybe used to an adjacent missed visit.

SAFETY ANALYSIS AND REPORTING

All safety analyses will be performed on all subjects enrolled and implanted with any TAR. Adverse events and other safety evaluations will be reported as frequency and rates as appropriate, cumulative over the different follow-up schedules. In addition to all patients, subgroup summaries ("standard instrumentation" and "approved additional instrumentation"), COFAS type, etc. will be presented. Adverse events and other safety evaluations will be reported as frequency and rates as appropriate, cumulative over the different follow-up schedules to each of the aforementioned surgical techniques.

1. Adverse Evets

Adverse Event (AE) is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device. All adverse events shall be reported in an interim and/or final report of the clinical investigation. Frequency of these complications will be summarized by according to Preferred Term (PT) and System Organ Class (SOC) using Medical Dictionary for Regulatory Affairs (MedDRA 18.0) .

The Investigator will follow up subjects who experience an AE until it is either resolved, determined to be chronic, stable, or, until the subject's participation in the study ends.
Prior to completion of the study, the Investigator will complete the Adverse Event Status Update Case Report Form to document any AE's previously reported as ongoing.

Intra-operative and post-operative complications, whether device-related or not, suspected or not complications will be reported as adverse events. Potential intraoperative and early postoperative complications, related to all total ankle replacements may include:

a. pain;
b. sudden drop in blood pressure intra-operatively due to the use of bone cement;
c. damage to blood vessels;
d. temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
e. cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
f. hematoma;

g. delayed wound healing; and
h. deep wound infection (early or late) which may necessitate removal of the prosthesis.
i. rarely an arthrodesis of the involved joint or amputation of the limb may be required.

Potential, late postoperative complications can include:
a. pain;
b. bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
c. peri-articular calcification or ossification, with or without impediment to joint mobility; and
d. inadequate range of motion due to improper selection or positioning of components or peri-articular calcification.

Additionally, these complications will be further categorized and reported as device related, or procedure related and outcome.

1. Serious Adverse Events (SAE)

A separate summary table of complications that met the serious adverse events (SAE) classification will be presented. Serious adverse events (SAE) as defined from ISO 14155:2011(E) Clinical Investigations of Medical Devices for Human Subjects – Good clinical practice, are any adverse events that:
a. Led to death;
b. Led to serious deterioration in the health of the subject, that either resulted in
c. A life-threatening illness or injury, or
d. A permanent impairment of a body structure or a body function, or
e. In-patient or prolonged hospitalization, or
f. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

2. Subsequent secondary surgical interventions

Adverse events that lead to secondary surgical intervention will be summarized, categorized by type of surgical intervention performed, namely: reoperation, reoperation with removal of implanted components, other interventions. The primary reason for the surgical intervention will be categorized as: implant failure, deep infection, aseptic loosening, subsidence, wound healing

problems, bone fracture, non-union and other reasons will also be tabulated in the same manner.

Other considerations

1. ***Outcome Measures Report Timing***

All analyses of outcome, except survivorship, will be done at each post-surgery visit namely: at 6 months, 1, 2, 3, 5, 7 years. The final analysis at 10 years will be done after all the subjects have completed final visit. In addition, at time points determined by the investigators and/or Wright Medical will be evaluated as needed or required for additional analysis of data for reporting and/or publication purposes will be done throughout the study.

2. ***Report Timing of survivorship assessment***

There will be two timepoints to assess and report survivorship, at the 5th (intermediate survivorship assessment) and 10th (long-term survivorship assessment) year follow-up.

At the intermediate assessment of survivorship (5th year follow-up), only patients with follow-up scores obtained at least four years after surgery will be included in the analysis. Patients who underwent reoperation or revision surgery with in four years of surgery will not be excluded.
At the final assessment of survivorship (10th year follow-up), only patients with follow-up scores obtained at least eight years after surgery will be included in the analysis. Patients who underwent reoperation or revision surgery with in eight years of surgery will not be excluded.

Missing Data

Missing data will not be imputed. Patients who were missing data required for a given analysis will be excluded.

STANDARD ELEMENTS

Wright Medical Technology, Inc. Page: # of #

Protocol US17-TAR-001

Title of Display
Study Population

<BODY OF DISPLAY>

Data Version: <date9> <program name>
Execution: <date9>

COMPUTING ENVIRONMENT

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

LISTING OF TABLES

LISTING OF LISTINGS

LISTING OF FIGURES