STATISTICAL ANALYSIS PLAN (SAP)

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1 LIST OF ABBREVIATIONS

Acronym	Term
ADE	Adverse Device Effect(s)
AE	Adverse Event(s)
AEMB	Adverse Event Monitoring Board
CI	Confidence Interval
CRF	Case Report Form(s)
DevD	Device Deficiency(ies)
EQ-5D	EuroQol 5D
FAS	Full Analysis Set
FU	Follow-Up
IQR	Interquartile Range
KSS	Knee Society Score
MRI	Magnetic Resonance Imaging
NA or N/A	Not Applicable
N (or n)	Total Sample Size (or subgroup sample size)
PP	Per-protocol Population
S+N	Smith & Nephew Inc.,/T. J. Smith & Nephew Ltd./Smith+Nephew Orthopedics/insert applicable Sponsor
SADE	Serious Adverse Device Effect(s)
SAE	Serious Adverse Event(s)
SAP	Statistical Analysis Plan
SAS	Safety Analysis Set
SD	Standard Deviation
TFL	Tables, Figures and Listing
TKA	Total knee Arthroplasty
USADE	Unanticipated Serious Adverse Device Effect(s)

2 INTRODUCTION

The following Statistical Analysis Plan (SAP) details the statistical considerations, including the data analysis methods, for the Study Protocol CORI Tensioner.2020.04. Related documents to this SAP are the Study Protocol, Case Report Form (CRF), and Tables, Figures and Listings (TFL) Templates Shells.

3 STUDY DESIGN

This is a post-market, prospective, multi-center, non-randomized, open-label study evaluating the performance of the CORI™ KNEE TENSIONER as an accessory to the CORI™ Surgical System. A minimum of 27 subjects having consented and underwent cemented primary TKA will be included. Approximately 4 sites will participate in the United States. The study is expected to enroll all subjects within a 15-month timeframe. Subject follow-up visits will be conducted at 6 weeks, 6 months and 12 months post-operatively.

4 STUDY OBJECTIVES

4.1 Primary Objective(s)

The primary objective of this study is to evaluate the performance of the CORI™ KNEE TENSIONER as an accessory to the CORI™ Surgical System by assessing patient satisfaction with the EQ-5D-5L Visual Analogue Scale (VAS).

4.2 Secondary Objective(s)

The secondary objective is to further evaluate patient satisfaction using additional scoring tools (i.e., the EQ-5D-5L Index score and the 2011 KSS Objective, Function and Satisfaction scores).

4.3 Exploratory Objective(s)

The exploratory objectives include other objectives outlined in the protocol which include evaluating the repeatability of the gap balancing workflow with the TENSIONER when compared to the surgeon's current, manual gap balancing technique. Additional objectives include generating data to support the creation of an optimized workflow for gap balancing with the TENSIONER as well as correlating soft tissue balance with subsequent implant placement changes.

5 STUDY ENDPOINTS

5.1 Primary Endpoint(s)

The primary endpoint of this study is the change from the preoperative to 12-month follow-up in EQ-5D-5L VAS.

5.2 Secondary Endpoint(s)

The following are the secondary endpoints defined for this study:

- The change from the preoperative to 12-month follow-up in EQ-5D-5L Index score.
- The change from the preoperative to 12-month follow-up in 2011 KSS Objective, Function, and Satisfaction scores
- Mean of the KSS Expectation scores at pre-operative and at 12- month follow-up

5.3 Exploratory Endpoint(s)

To evaluate the repeatability, within the same deformity profile, of gap planning with the TENSIONER when compared to the surgeon's manual gap balancing technique.

The following endpoints have been defined for this study in order to support the creation of an optimized gap balancing workflow.

- Medial-to-lateral balance measurements at 0/10°, 30°, 60°, and 90° flexion.
- Implant position alignment and resection depths.
- Incidence and details of soft tissue release.
- Analysis of force and deformity data (i.e., deformities outside the given range).

5.4 Safety Endpoint(s)

Safety endpoints include the collection of the following:

- All AEs and complications occurring from the time of subject enrolment until study termination or study completion including intra-operative AEs and complications.
- Device related re-intervention.
- Device Deficiencies (DD).

6 STATISTICAL CONSIDERATIONS

6.1 Determination of Sample Size

The sample size was determined using a Bayesian approach. Prior information for Bayesian sample size determination was obtained from a systematic literature review and meta-analysis. Lower limit of the 95% confidence interval of the studies was used to derive the meta-analysis summary result for conservativeness. The meta analysis summary result presented a mean change of EQ-5D VAS score at 12 months against baseline of 11.977 (4.879 - 19.076, 95% confidence interval), and a SD of 17.743. To determine sample size, a simulation approach was used. Change scores were generated from multiple random samples from the normal distribution with mean and SD from the meta-analysis result, i.e. Normal (11.977, 17.743). A Bayesian model was then fitted to these scores, using a conservative normal prior based on the lower 95% CI limit of change in EQ-5D from the meta analysis result, i.e. Normal (4.879, 17.743). A Cauchy prior (0, 17.743) was used as the prior for the standard deviation to account for variability. Significance against 0 will be concluded if the lower limit of the two-sided 95% Highest Density Credible Interval (HDI) for the posterior distribution is > 0. This simulation process was repeated across 50 iterations to estimate statistical power.

To achieve 80% power, 20 evaluable subjects are required. To allow for up to 25% attrition due to loss to follow-up, a minimum of 27 subjects will need to be enrolled with a maximum of 83 based on those consented under frequentist sample size calculations in Protocol Version 3.0.

6.2 Randomisation

No randomization has been planned for this study as it is non-comparative.

6.3 Interim Analysis

No interim analyses are planned for this study.

7 STATISTICAL ANALYSIS

7.1 General

Smith+Nephew's Global Biostatistics group will conduct the statistical analysis for this study. Unless otherwise stated, analyses will follow a Bayesian framework. Results will be reported as posterior medians with 95% credible intervals, and posterior probabilities for exceeding pre-specified thresholds will be presented. A threshold of 0.975 will generally be used for one-sided decisions. No frequentist p-values will be reported unless explicitly stated.

Where data summaries are specified, categorical and ordinal variables will be summarized with frequencies and percentages. Continuous variables will be summarized with the following summary statistics: number of observations, mean, median, standard deviation, minimum and maximum values. All analyses will be performed in SAS, version 9.4 (or later) or R (http://www.r-project.org), version 4.5.1.

7.2 Analysis Populations

The following analysis populations will be used for this study:

- Safety Population (SAF), including all subjects who have received IP.
- Full analysis set population (FAS), all subjects who were enrolled into the study and had at least one post-baseline effectiveness assessment
- Per-Protocol Population (PP), including all subjects in the full analysis set who have no significant protocol deviations and met all inclusion/exclusion criteria.

All baseline disposition and demographic tables will be produced for all three analysis populations. The VAS component analysis, radiographic assessment, safety and protocol deviation tables will be given for the SAF population. Tables for Patient-Reported Outcome Measures (PROMs) will be provided for both the FAS and PP populations.

7.3 Handling of Missing, Incomplete and Repeat Data

Only observed data will be reported.

7.4 Derived Data

Analysis of populations

- Flag for inclusion in the SAF population
- Flag for inclusion in the FAS population
- Flag for inclusion in the PP population

Change from pre to postoperative visits

This will be calculated as:

- Post−operative value$visit\ n$ − Pre−operative value($Visit\ 1$) $where\ n > 1$.

Body Mass Index (BMI)

- BMI = {(Weight in kg)/(Height in m)^2}, if units are in kg for weight and m for height
- BMI = {(Weight in lbs.)x703.07))/(Height in inches)}, if units are in lbs. for weight and inches for height (Adjustments made to formula to standardize BMI unit to kg/m^2)

Five-level Euro QoL five-dimensional score (EQ-5D-5L)

The classification system for the EQ-5D-5L[1] is comprised of five dimensions, namely mobility, selfcare, usual activities, pain/discomfort and anxiety/depression with each of the dimensions having five levels: "no problem" (level 1), "slight problems" (level 2), "moderate problems" (level 3), " severe problems" (level 4), and "extreme problems" (level 5). Hence, the system defines 3125 (5^5) health states ranging from 11111 to 55555 (i.e. the best possible health state to the worst possible health state).

- The individual domain responses on each of the 5 levels cale of 1-5 will be combined based on the levels scored combining the domains to form a 5-digit number in the form XXXXX (where X is 1-5) describing the respondent's health state as previously described. The EQ-5D-5L index value would be derived by using the vendor supplied calculator in Microsoft Excel to convert each 5-digit EQ-5D-5L profile.

KSS

The 2011 Knee Society Score[2] consists of 34 questions and provides sub-scores across 5 dimensions as shown in Table 1.

Table 1

2011 Knee Society Score

#	Sub-Score	# Questions	Range	Completion by
1	Objective Knee Score	7	0-100	Surgeon
2	Subject Satisfaction Score	5	0-40	Subject
3	Subject Expectation	3	3-15	Subject
4	Functional Knee Score	19	0-100	Subject

The Knee Society Score (KSS) comprises information on Objective Knee Indicators (range 0 to 100 points), Patient Satisfaction (range 0-40), Patient Expectation (range 0-15), and Functional Activities (range 0-100). The KSS endpoints are derived from a series of questions that relate to everyday activities. More elaborate information for deriving the KSS endpoints are described in the publication by Scuderi et al (2012)[1]. However, an abbreviated description of the KSS endpoints used in the study is described in this SAP.

Objective Knee Score (Completed by Physician/Surgeon):

The objective score allows for more than 100 points in patients with greater than 125° of flexion and a stable painless knee as outlined below:

- "Alignment" allows for a maximum of 25 points and is determined on a weight-bearing AP radiograph measuring the femoral-tibial (Anatomic) axis.
- "Instability" allows for a maximum of 25 points for a knee that is stable in the coronal and saggital axis.
- "Joint Motion" allows one point for each 5° of joint motion with a potential for greater than 25 points to be assigned for patients with greater than 125° of motion. There are deductions for flexion contracture and extension lag.
- "Instability" has a maximum allowable point allocation of 25+.
- "Symptoms" category contains two 10-level scales, ranging from "none" to "severe" for each patient to rate pain encountered when walking on level ground and on stairs/inclines. For this, a patient starts with 10 points on each scale for a painless knee with deductions of up to 10 points deductions as indicated by the patient's response on each pain scale. There is an additional question regarding how "normal" the knee feels to the patient. The maximum allowable point is 25.

Patient Expectations and Satisfaction (Completed by Patient)

- "Patient Expectations" is a three-question fifteen-point scale that is collected pre-operatively and post-operatively. The pre-operative questions reflect a patient's opinion on the extent to which s/he expects that the operation will improve his/her knee pain, and the ability to perform activities of daily living and recreational activities.

- The post-operative patient expectations questions reflect the extent to which the outcome after the operation has met the patient's pre-operative expectations with respect to pain and function.
- "Patient Satisfaction" is a five-question 40-point scale that is collected preoperatively and at each follow-up visit.

Functional Score (Completed by Patient)

The functional score is composed of the four subgroups and has a maximum score of 100 as follows:

- "Walking and Standing" has a maximum value of 30 points with deductions for the use of walking aids and supports.
- "Standard Activities" has a maximum of 30 points and evaluates "standard" activities of daily living. Patients can also respond if they never participate in the activities. Patients who respond "I never do this" receive zero points for that activity.
- "Advanced Activities" has a maximum of 25 points and evaluates function in performing more vigorous activities ranging from climbing a ladder or step-stool to running. Patients can also respond if they never participate in the activities. Patients who respond "I never do this" receive zero points for that activity.
- "Discretionary Activities" has a maximum of 15 points and allows patients to select the three activities that they consider most important to them personally from a group of seventeen recreational and exercise activities. Patients who do not participate in any of the discretionary activities will have a functional knee score that is limited to 85 points. The discretionary activities do not need to be identical in the pre-operative and post-operative period.

<u>Adverse Events</u>

Investigator events do not receive a classification and so S+N classify events as follows:

- An event will be classified as an ADE if the relationship to the study device and/or the relationship to the study procedure is possibly/definitely
- An event will be classified as an SAE if the event is serious
- An event will be classified as an SADE if it is an ADE which is also serious
- An event will be classified as a USADE if it is an SADE which is also unanticipated
- Otherwise, the event will be a non-device, non-procedure related, non-serious AE

For adverse events that have been resolved, duration of adverse event is calculated as end date minus start date

Due to system updates, checks need to be performed to ensure the most stringent classification is being reported. When comparing Investigator assessments (classifications as above) with AEMB classifications, the most stringent classification should be reported as follows:

Investigator assessment	AEMB classification	Most stringent
AE	SAE	SAE

SAE	AE	SAE
AE	ADE	ADE
ADE	AE	ADE
ADE	SADE	SADE
SADE	ADE	SADE
SAE	SADE	SADE
SADE	SAE	SADE
SADE	USADE	USADE
USADE	SADE	Obtained from Medical Affairs and Investigator

7.5 Baseline Data

Preoperative or operative variables will be summarized using descriptive characteristics for continuous or categorical data as applicable.

- Age (in years),
- Sex (males or females),
- Childbearing potential
- Ethnicity
- Race
- Body Mass Index (BMI),
- Components of the device implanted.
- Presence or osteophytes.
- Surgical approach used.
- Side of implantation (left versus right)
- CORI Robotic Packaging Status
- Intra-operative complications related to the use of the CORI robotics system

Variables summarized will not only be restricted to the above listed but on all variables deemed pertinent and obtainable preoperatively and operatively. Additionally, age will be categorically summarized by stratifying into: < 60 years versus ≥ 60 years. BMI will also be categorically summarized by stratifying into: < 30 kg/m2 versus ≥ 30 kg/m2.

7.6 Disposition Data

The number of subjects that enter the study, and the number of subjects/knees with follow up information will be provided by visit:

- Theoretically due: number enrolled and implanted with study device
- Deaths: cumulative number of subjects that died prior to the study visit
- Revisions / failures: cumulative number of subjects/knees that revised/failed prior to the study visit
- Cumulative terminations: terminated from study other than from revision or death
- Expected = theoretical due – cumulative (deaths + revisions + termination)
- Actual = actual number of subjects/knees at follow up visit

- Follow up = actual / expected x 100.

The number of subjects that have discontinued from the study and reasons for withdrawal will be summarised.

Study duration and the duration between surgery and each visit will be summarised.

Screening and enrolment summary: For each centre/site, dates that the first subject was screened/enrolled and the last subject completed will be provided, duration (site, 1st enrolled – final subject exit), together with number of subjects enrolled and number of subjects completed 1 year visit.

7.7 Protocol Deviations

The frequency of protocol deviations will be summarized along with the number of subjects experiencing each.

7.8 Measurement of Treatment Compliance

Not applicable.

7.9 Multiplicity

No adjustments for multiplicity are planned for this study.

7.10 Analysis of Primary Endpoint(s)

EQ5D-5L VAS Score

- The EQ5D-5L VAS score will be summarized using summary statistics at the preoperative visit, 6 weeks visit, 6 months visit, and the 12-month postoperative visit. The change in scores from baseline (preoperative) to postoperative follow-up visits will also be summarized.
- The primary endpoint of the study is the change in EQ5D-5L VAS score from baseline at 12 months. A Bayesian model will be used for the primary endpoint analysis. The exact conservative prior distribution selection from the meta-analysis result of the sample size calculation (section 6.1) will be used for this Bayesian model. That is, the conservative normal prior will be used as the lower 95% CI limit of change in EQ-5D from the meta-analysis result, i.e. Normal (4.879, 17.743). The same Cauchy prior (0, 17.743) will be used as the prior for the standard deviation to account for variability. The posterior distribution of the treatment effect will be summarized using the posterior mean, median and 95% Highest Density Credible Interval (HDI). Significance against 0 will be concluded if the lower limit of the two-sided 95% Highest Density Credible Interval (HDI) for the posterior distribution is > 0. MCMC sampling method in Stan package will be used to estimate the posterior distribution.
- Primary analysis will be analyzed using the FAS population. Sensitivity analysis will be analyzed using the PP and SAF population.

7.11 Analysis of Secondary Endpoint(s)

All secondary endpoints will be summarized using the FAS and PP population.

EQ5D-5L Score

- The HRQoL Index score derived from EQ-5D-5L will be summarized using summary statistics at the preoperative visit, 6 weeks visit, 6 months visit, and the 12-month postoperative visit.
- The change in scores from baseline (preoperative) to postoperative follow-up visit will also be summarized. A paired t-test will be used to assess if change from pre-operative to the 12- month follow-up EQ-5D-5L index scores are significantly greater than 0 (i.e., $\mu 1-\mu 0 > 0$). If the lower limit of the two-sided 95% CI for ($\mu 1-\mu 0$) from the t-statistic is > 0, then it will be concluded that the change is significantly different from 0.

KSS score

- The overall KSS 2011 and its four subscores (Objective, Satisfaction, Expectation and Function) will be summarized using summary statistics for continuous variables at the preoperative visit, 6 weeks visit, 6 months visit, and the 12-month postoperative visit.
- The change in scores from baseline (preoperative) to postoperative follow-up will also be summarized The analyses for these scores will be analogous to that specified for the EQ-5D index score.
- The KSS Expectation score will be summarized descriptively at the preoperative and follow-up visits using summary characteristic for continuous variables.

7.12 Analysis of Exploratory Endpoint(s)

Medial-to-lateral balance measurements

- Medial to lateral balance measurements at 0^0, 10^0, 30^0, 60^0 and 90^0 flexion will be summarized using descriptive statistics (mean, standard deviation, median, minimum, maximum and interquartile rang). Results will be presented separately for the TENSIONER device and for the surgeon's manual gap balancing technique.

Implant position alignment and resection depths

- Implant position alignment and resection depths will be summarized descriptively. Results will be presented separately for the TENSIONER device and for the surgeon's manual gap balancing technique.

Incidence and details of soft tissues release

- Incidence and details of soft tissue release will be tabulated by frequency and percentage. Results will be presented separately for the TENSIONER device and for the surgeon's manual gap balancing technique.

Force and deformity data

- Force and deformity data will be summarized descriptively. Out-of-range deformities will be identified, and the distributions of these deviations will be presented.

7.13 Analysis of Safety Endpoint(s)

Adverse Events

Adverse event table summaries will be provided using the most stringent classification from Investigator and Adverse Event Monitoring Board (AEMB). Both Investigator and AEMB classifications will be provided alongside the most stringent classification in the Listings.

The number of events and the number of subjects reporting: adverse events (AE) and serious adverse events (SAE), adverse device effects (ADE), serious adverse device (SADE) and unanticipated serious adverse device effects (USADE) will be summarised.

In addition, AEs will be summarised by: frequency, severity, anticipated/unanticipated, relationship to device and procedure; treatment and surgical intervention details (type, reason), outcome and duration of adverse events at trial discontinuation will be summarised.

AEs will be coded using IMDRF coding dictionary and the System Organ Class and Term will be presented by serious and non-serious events.

Device related re-intervention

Defined as any surgical procedure involving the study device after the implantation surgery. For each re-intervention, the following will be recorded and summarized:

- Component involved (femoral, tibial, etc)
- Fixation status (i.e well-fixed)
- Presence of damage
- Type of procedure (removed, revised)
- Component disposition (returned to the manufacturer, retained at site/hospital, destroyed, etc)

Device Deficiencies

The number of device deficiencies, and the number with potential to cause an SAE will be summarised.

7.14 Other Data Summaries

Not applicable.

8 CHANGES IN ANALYSIS METHODS SPECIFIED IN THE PROTOCOL

Not applicable.

9 TABLE TEMPLATES

The following mock table layouts represent the key outputs planned for this study. They include both categorical and continuous endpoints, stratified by implant component when relevant, and cover descriptive statistics as well as statistical analyses. All baseline disposition and demographic tables will be produced for all three analysis populations. The radiographic assessment, safety and protocol deviation tables will be given for the SAF population. Tables for Patient-Reported Outcome Measures (PROMs) will be provided for both the FAS and PP populations.

For all tables included in the analysis, the number of subjects must be presented. If it is not feasible to display this information within the table itself, it should be provided in a footnote, as appropriate.

Table X. Summary of subjects/ knees at enrollment

Characteristics	**Total**
Subjects	
Total subjects enrolled (N)	XX.X (XX.XX)
Number of subjects in Safety Population	XX.X (XX.XX)
Number of subjects in Full Analysis Population	XX.X (XX.XX)
Number of subjects in Per protocol Analysis Population	XX.X (XX.XX)
Knees	
Total Knees enrolled (N)	
Left knees	XX.X (XX.XX)
Right knees	XX.X (XX.XX)
Number of knees in Safety Population	
Left knees	XX.X (XX.XX)
Right knees	XX.X (XX.XX)
Number of knees in Full Analysis Population	
Left knees	XX.X (XX.XX)
Right knees	XX.X (XX.XX)

Table X. Demographics

Characteristics	Total
Age (years)	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
Age (years) (categorical)	
< 60	XX.X (XX.XX)
>= 60	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Weight (kg)	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
Height (cm)	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX

Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
BMI (kg/m2)	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
BMI (kg/m2) (categorical)	
< 60	XX.X (XX.XX)
>= 60	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Sex	
Male	XX.X (XX.XX)
Female	XX.X (XX.XX)
Undifferentiated	XX.X (XX.XX)
Unknown	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Childbearing Status	
Yes	XX.X (XX.XX)
No	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Ethnicity	
Hispanic or Latino	XX.X (XX.XX)
Not Hispanic or Latino	XX.X (XX.XX)
Not Reported	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)

Race	
American Indian or Alaska Native	XX.X (XX.XX)
Asian	XX.X (XX.XX)
Black or African American	XX.X (XX.XX)
White	XX.X (XX.XX)
Not Reported	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Asian race detail	
Asian Indian	XX.X (XX.XX)
Chinese	XX.X (XX.XX)
Japanese	XX.X (XX.XX)
Korean	XX.X (XX.XX)
Southeast Asian	XX.X (XX.XX)
Native Hawaiian or Other Pacific Islander	XX.X (XX.XX)
Other Asian	XX.X (XX.XX)
N	XX.X (XX.XX)
If Southeast Asian, specify	
Singaporean	XX.X (XX.XX)
Indonesians	XX.X (XX.XX)
Thai	XX.X (XX.XX)
Cambodians	XX.X (XX.XX)
Laotians	XX.X (XX.XX)
Malaysians	XX.X (XX.XX)
Filipino	XX.X (XX.XX)
Vietnamese	XX.X (XX.XX)
Myanmarese	XX.X (XX.XX)
Bruneian	XX.X (XX.XX)
Timor Lestian	XX.X (XX.XX)
Other Southeast Asian	XX.X (XX.XX)
N	XX.X (XX.XX)
Substance use	
Tobacco	XX.X (XX.XX)
Alcohol	XX.X (XX.XX)
Caffeine	XX.X (XX.XX)
Drugs	XX.X (XX.XX)
N	XX.X (XX.XX)
Usage	

Former	XX.X (XX.XX)
Current	XX.X (XX.XX)
N	XX.X (XX.XX)
Urine Pregnancy Test Result	
Positive	XX.X (XX.XX)
Negative	XX.X (XX.XX)
N	XX.X (XX.XX)
Stage of Pregnancy, if applicable	
First trimester	XX.X (XX.XX)
Second trimester	XX.X (XX.XX)
Third trimester	XX.X (XX.XX)
N	XX.X (XX.XX)

Table X. Operative characteristics

Characteristics	**Total**
Diagnosis	
Osteoarthritis	XX.X (XX.XX)
Avascular necrosis	XX.X (XX.XX)
Rheumatoid arthritis	XX.X (XX.XX)
Functional deformity	XX.X (XX.XX)
Fractures that were unmanageable using other techniques	XX.X (XX.XX)
Other joint disease or deformity	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Type of Bone Removal Technique	
Burr all	XX.X (XX.XX)
Distal precision burring	XX.X (XX.XX)
Other	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Cut order	
Distal curt first	XX.X (XX.XX)
Tibial curt first	XX.X (XX.XX)
Other	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)

Total Blood Loss (ML)	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
Blood Loss Prevention Method	
Tourniquet	XX.X (XX.XX)
Mechanical	XX.X (XX.XX)
Oher	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Presence of osteophytes	
Femoral	XX.X (XX.XX)
Tibial	XX.X (XX.XX)
Patellar	XX.X (XX.XX)
None	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Osteophytes removed	
Yes	XX.X (XX.XX)
No	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Packaging for all CORI products intact	
Yes	XX.X (XX.XX)
No	XX.X (XX.XX)
Missing	XX.X (XX.XX)
N	XX.X (XX.XX)
Any intraoperative problems related to the use of CORI robotics system	
Yes	XX.X (XX.XX)
No	XX.X (XX.XX)
Missing	XX.X (XX.XX)

N	XX.X (XX.XX)

Table X. EQ-5D-5L VAS Score (primary endpoint)–

Assessment	**Total**
Screening/Pre-operative	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
6-week assessment	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
6-month assessment	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX

12-month assessment	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX

Table X. EQ-5D-5L VAS Score – Change from Baseline (primary endpoint)–

Assessment	**Total**	**95% Confidence Intervals**
6-week assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	
6-month assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	

12-month assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	

Table X. EQ-5D-5L VAS Score – Change from Baseline at 12 Months with Bayesian Model (primary endpoint)–

Assessment	**Total**
12-month assessment Posterior Distribution	
Mean	XX
95% Lower HDI CI	XX
95% Upper HDI CI	XX
Missing	XX
N	XX

Table X. EQ-5D-5 Index Score

An equivalent table summarizing the KSS score will also be included.

Assessment	**Total**
Screening/Pre-operative	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
6-week assessment	

Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
6-month assessment	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX
12-month assessment	
Mean	XX
Median	XX
Std	XX
Min	XX
Max	XX
Q1	XX
Q3	XX
Inter Quartile Range	XX
Missing	XX
N	XX

Table X. EQ-5D-5 Index Score, Change from the baseline

An equivalent table summarizing the KSS score will also be included.

Assessment	**Total**	**95% Confidence Intervals**

6-week assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	
6-month assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	
12-month assessment		
Mean	XX	
Median	XX	
Std	XX	
Min	XX	
Max	XX	
Q1	XX	
Q3	XX	
Inter Quartile Range	XX	
Missing	XX	
N	XX	

Table X. Adverse events reporting most stringent of Investigator / Sponsor - Event level

	Total
Total number of events	XX
Total number of serious events (SAE or SADE or USADE)	XX

Most Stringent Classification	XX
Number of AE	XX
Number of SAE	XX
Number of ADE	XX
Number of SADE	XX
Number of USADE	XX
Number of ADE and Device Related (Investigator or Sponsor)	XX
Number of ADE and Procedure Related (Investigator or Sponsor)	XX
Number of ADE and Device and Procedure Related (Investigator or Sponsor)	XX
Number of SADE and Device Related (Investigator or Sponsor)	XX
Number of SADE and Procedure Related (Investigator or Sponsor)	XX
Number of SADE and Device and Procedure Related (Investigator or Sponsor)	XX

Table X. Adverse events reporting most stringent of Investigator / Sponsor – Subject level

	Total
Total number of subjects reporting an event	XX
Total number of subjects reporting a serious event (SAE or SADE or USADE)	XX
Most Stringent Classification	XX
Number of subjects experiencing AE	XX
Number of subjects experiencing SAE	XX
Number of subjects experiencing ADE	XX
Number of subjects experiencing SADE	XX
Number of subjects experiencing USADE	XX
Number of subjects with ADE and Device Related (Investigator or Sponsor)	XX
Number of subjects with ADE and Procedure Related (Investigator or Sponsor)	XX
Number of subjects with ADE and Device and Procedure Related (Investigator or Sponsor)	XX
Number of subjects with SADE and Device Related (Investigator or Sponsor)	XX
Number of subjects with SADE and Procedure Related (Investigator or Sponsor)	XX
Number of subjects with SADE and Device and Procedure Related (Investigator or Sponsor)	XX

10 REFERENCES

1. Scalone, Luciana et al. Italian Population-Based Values of EQ-5D Health States. Value in Health , Volume 16 , Issue 5 , 814 – 822

2. Scuderi, Giles R. et al. "The New Knee Society Knee Scoring System." Clinical Orthopedics and Related Research 470.1 (2012): 3–19. PMC. Web. 25 June 2018.

Certificate Of Completion

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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

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Envelope Sent	Hashed/Encrypted	24-Sep-2025 | 20:50
Certified Delivered	Security Checked	24-Sep-2025 | 20:51
Signing Complete	Security Checked	24-Sep-2025 | 20:51
Completed	Security Checked	03-Oct-2025 | 23:04

Payment Events	Status	Timestamps