Follow-Up of Subjects with a Journey® UNI Unicompartmental Knee System Implant

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ABBREVIATIONS

AE	Adverse Event(s)
ADE	Adverse Device Effect(s)
AOA	Australian Orthopaedic Association
AP	AnteroPosterior
BMI	Body Mass Index
CE	Conformité Européene
CRF	Case Report Form(s)
DevD	Device Deficiency(ies)
EC	Ethics Committee
EQ-5D	EuroQol Five Dimension
FJS	Forgotten Joint Score
GCP	Good Clinical Practice
HTO	High Tibial Osteotomy
ICF	Informed Consent Form
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent to Treat
KSS	Knee Scoring System/Knee Society Score
LTFU	Lost to Follow-up
NIDJD	Non-Inflammatory Degenerative Joint Disease
OA	Osteoarthritis
PI	Principal Investigator
PMCF	Post-Market Clinical Follow-Up
PP	Per-protocol Population
PRO	Patient-Reported Outcome
QoL	Quality of Life
ROM	Range of Motion
SAE	Serious Adverse Event(s)
SADE	Serious Adverse Device Effect(s)
SAP	Statistical Analysis Plan
SAPSS	Self-Administered Patient Satisfaction Survey
SAS	Statistical Analysis System
TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
UHMWPE	Ultra-High Molecular Weight Polyethylene
UKA	Unicompartmental Knee Arthroplasty
UKS	Unicompartmental Knee System
USADE	Unanticipated Serious Adverse Device Effect(s)
VAS	Visual Analog Scale

Protocol Synopsis

Title of Study:	**Follow-Up of Subjects with a Journey° UNI Unicompartmental Knee System Implant**
Study Type:	Post-Market Clinical Follow-up (PMCF)
Study Device:	Journey UNI Unicompartmental Knee System (UKS) (femoral component, tibial baseplate, and tibial insert)
Indications	Unicompartmental Knee Implants are indicated for restoring either compartment of a knee • affected by non-inflammatory degenerative joint disease (NIDJD) including osteoarthritis (OA), traumatic arthritis, or avascular necrosis • for correction of functional deformity • as a revision procedure where other treatments or devices have failed • to repair fractures that are unmanageable using other techniques
Study design:	Retrospective/Prospective follow-up of subjects who previously had the device implanted
Primary Endpoint:	Implant survival 5 years postoperatively
Secondary Endpoints:	<u>Effectiveness</u> Function will be assessed at multiple time points via: • The 2011 Knee Society Score (KSS) • EuroQol Five Dimensions Questionnaire (EQ-5D-5L) • Self-Administered Patient Satisfaction Survey (SAPSS) • Forgotten Joint Score (FJS) <u>Safety</u> • Device-related adverse events (AE), as indicated by the investigator • Radiographic findings
Length of Study:	Up to 6 years
Number of Sites:	Approximately 10 clinical sites
Sample Size:	147 knees
Inclusion Criteria:	1. Between 12 and 48 months previously, subject had unicompartmental knee replacement implanted for unicompartmental, NIDJD including OA, traumatic arthritis, avascular necrosis, for correction of functional deformity, or to repair a fracture that was unmanageable using other techniques. 2. Subject received a Journey UKS implant (consisting of a femoral component, tibial baseplate, and a tibial insert). 3. Subject was considered skeletally mature at the time of surgery and was at least 18 years of age. 4. Subject is willing to have retrospective data collected and to participate in required prospective follow-up visit(s) at the investigational site and to complete study procedures and questionnaires.

	5. Subject has consented to participate in the study by signing the Institutional Review Board (IRB)/Ethics Committee (EC)-approved informed consent form (ICF).
Exclusion Criteria:	1. Subject has Body Mass Index (BMI) > 40 within 1 month of surgery. 2. Subjects who have received the Journey UNI UKS as part of a revision surgery. 3. Subject has a condition that may interfere with the unicompartmental knee arthroplasty (UKA) survival or outcome (e.g. Paget's or Charcot's disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease). 4. Subject has a known allergy to study device or one or more of its components. 5. Subject, in the opinion of the Principal Investigator (PI), has an emotional or neurological condition that would preempt his/her ability or willingness to participate in the study including mental illness, mental retardation, drug or alcohol abuse. 6. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product in the past 30 days. 7. Subject is known to be at risk for loss to follow-up, or failure to return for scheduled visits.

1. BACKGROUND AND STUDY RATIONALE

1.1 BACKGROUND

Severe knee Osteoarthritis (OA) is an important cause of pain, disability, and loss of quality of life. OA is a joint disease that mostly affects cartilage. Symptoms can include pain, stiffness, and swelling, reduced range of motion, and ultimately, deformed joints. OA can be treated through non-operative methods including weight loss and strengthening[1], bracing[2], and oral analgesics or anti-inflammatory medications[3-5]. The knee joint, the joint most commonly affected by OA[6], can also be treated with intra-articular corticoid or hyaluronic acid injections[7]. When these treatment options are no longer sufficiently effective, surgical intervention is recommended.

The options for surgical treatment of knee OA depend on the area of the knee that is affected. The knee is composed of three compartments that can be affected by OA: the medial femoral condyle, the lateral femoral condyle, and the patellofemoral region. If OA affects only one compartment, it may be possible to have a unicompartmental or partial replacement.

Of patients with knee OA, about one-third has OA of only one compartment. Of this patient subset, two-thirds involve only the patellofemoral region, one-third involves the medial compartment, and approximately 3% involve only the lateral compartment[8].

For unicompartmental OA of the medial or lateral compartment, surgical options include high tibial osteotomy (HTO), unicompartmental knee arthroplasty (UKA), and total knee arthroplasty (TKA). TKA can also be performed when only one compartment is involved; however, this results in the removal of bone from non-affected compartments.

UKA is considered less traumatic, as only the affected compartment is replaced, the surgery is less invasive, there is less bone removed, and typically less disturbance to the tissue surrounding the knee than in traditional knee replacement surgery. A systematic review was performed by Griffin, et al[9], comparing HTO, UKA, and TKA outcomes. They determined that 10-year survivorship of the implant was less than 85% for HTO, 85-95% for UKA, and approximately 90% for TKA. There were more complications with HTO than UKA. The range of motion was better with UKA compared to TKA. Additionally, lower blood loss has been reported with UKA compared to TKA[10].

According to the American Academy of Orthopedic Surgeons[11], partial knee replacement patients usually spend less time in the hospital, have lower blood loss, and return to normal activities sooner than total knee replacement (TKR) patients. Partial knee replacement patients may also experience better early flexion, less pain after surgery and experience a more natural-feeling outcome.

The purpose of the current investigation is to assess the safety and effectiveness of the JOURNEY UNI Unicompartmental Knee System (UKS) in patients with non-inflammatory degenerative joint disease (NIDJD) of the knee who previously had the Journey UNI UKS implanted.

1.2 STUDY RATIONALE

This clinical study will prospectively evaluate the 36- and 60-month safety and performance of the JOURNEY UNI UKS in patients with NIDJD of the knee who required lateral or medial knee compartment replacement.

2. Study Objectives

To assess the safety and effectiveness of the JOURNEY UNI UKS in subjects with unicompartmental degeneration of the knee who previously had the JOURNEY UNI UKS implanted, and to test non-inferiority of the cumulative percent implant survival compared to a literature reference rate of 91.7% (Australian Orthopaedic Association [AOA] National Joint Replacement Registry Annual Report 2015)[12] at 5 years.

2.1 PRIMARY ENDPOINT

Implant survival 5 years postoperatively.

2.2 SECONDARY ENDPOINTS

Effectiveness

- 2011 Knee Society Score (KSS)
- The EuroQol Five Dimensions Questionnaire (EQ-5D-5L)
- Self-Administered Patient Satisfaction Survey (SAPSS) for Primary Hip and Knee Arthroplasty
- Forgotten Joint Score (FJS)

Safety

- Device-related (as indicated by the Investigator) adverse events (AE)
- Radiographic findings

3. Study Design

This is a retrospective/prospective, open-label single cohort, multicenter study to collect relevant clinical data on 147 knees with unicompartmental degeneration of the knee, in which the Journey UNI UKS was previously implanted.

Data from eligible subjects will be recorded from the subject's medical record onto case report forms (CRFs) with the exception of Patient-Reported Outcomes (PROs) per section 12.1.

Approximately 10 clinical sites in the United States and Canada will enroll 147 knees that meet the study criteria.

Two prospective follow-up clinical assessments will be performed. The first will occur 36 (± 12) months postoperatively and the second will occur 60 (± 12) months postoperatively.

The total study duration will be approximately 6 years.

4. Study Device

The Journey UNI UKS is a CE marked and 510K cleared medical device. The device has been designed to treat both medial and lateral unicompartmental disease. It is a comprehensive system designed to allow surgeons to perform UKA. The Journey UNI system is a cemented implant; the 3 primary planar surfaces are aligned with the mechanical axis of the femur. The cement interface surface is grit-blasted.

The Journey UNI is comprised of the following anatomic components:

- Journey UNI Oxidized zirconium or CoCr alloy femoral components
- Journey UNI Titanium 6Al-4V alloy or ultra-high molecular weight polyethylene (UHMWPE) tibial baseplate
- Journey UNI UHMWPE tibial insert

Figure 4-1: JOURNEY UNI Components



Only patients receiving femoral components, tibial components, and tibial inserts from the JOURNEY UNI UKS are eligible for study enrollment.

4.1 Surgical Technique

Not applicable, as subjects in this study will have already undergone surgery.

4.2 Device Accountability

Not applicable, as no new devices will be supplied or implanted during this study.

5. Study Population

5.1 Subject Screening and Enrollment

Investigators will pre-screen all subjects that have previously undergone UKA using the Journey UNI UKS system between 12 and 48 months previously using only the existing information in the medical records.

Investigators will contact subjects identified in this pre-screening to determine their interest in participating in the study. No study-specific procedures, activities, or questionnaires will be performed during pre-screening.

Once a subject has completed the informed consent process, which includes signing the ICF, the Principal Investigator (PI) or delegated study research staff should complete the screening process with the subject. All potential subjects who undergo the screening process will have their information documented on a Screening and Enrollment Log, with the reason for exclusion noted, if applicable.

If during screening, a subject is found to have had a revision of the Journey UNI UKS device, the subject is still eligible to be enrolled in the study.

5.2 Randomization and Blinding

Not applicable, the study is not blinded.

5.3 Subject Inclusion Criteria

1. Between 12 and 48 months previously, subject had unicompartmental knee replacement implanted for unicompartmental, NIDJD including OA, traumatic arthritis, avascular necrosis, for correction of functional deformity, or to a repair a fracture that was unmanageable using other techniques.
2. Subject received a knee implant consisting of a femoral component, tibial baseplate, and a tibial insert from the JOURNEY UNI UKS.
3. Subject was considered skeletally mature at the time of surgery and was at least 18 years of age.
4. Subject is willing to have retrospective data collected and to participate in required prospective follow-up visit(s) at the investigational site and to complete study procedures and questionnaires.
5. Subject has consented to participate in the study by signing the Institutional Review Board (IRB)/Ethics Committee (EC)-approved ICF.

5.4 Subject Exclusion Criteria

1. Subject has Body Mass Index (BMI) > 40 within 1 month of surgery.
2. Subjects who have received the Journey UNI UKS as part of a revision surgery.
3. Subject has a condition that may interfere with the UKA survival or outcome (e.g. Paget's or Charcot's disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease).
4. Subject has a known allergy to study device or one or more of its components.
5. Subject, in the opinion of the PI, has an emotional or neurological condition that would preempt his/her ability or willingness to participate in the study including mental illness, mental retardation, drug, or alcohol abuse.
6. Subject is entered in another investigational drug, biologic, or device study or has been treated with an investigational product in the past 30 days.
7. Subject is known to be at risk for loss to follow-up, or failure to return for scheduled visits.

6. Study Procedures

6.1 STUDY SCHEMATIC

Table 6.1-1 provides an overview of the schedule of visits and data that will be collected.

Table 6.1-1: Study Procedures by Visit

Visit	1[a]	2[a]	3
Schedule of events	**Initial**	**36 (± 12) Months**	**60 (± 12) Months**
Informed Consent	√		
Inclusion/Exclusion	√		
Demographics/Medical History	√		
Operative/Discharge Information	√		
Radiographic Data/Assessment	√[b]	√	√
KSS	√[b]	√	√
EQ-5D-5L	√[b]	√	√
SAPSS	√[b]	√	√
FJS	√[b]	√	√
Implant Disposition	√[c]	√[c]	√[c]
Adverse Events	√[d]	√[d]	√[d]
End of Study: Subject Disposition	√[c]	√[c]	√[d]

[a] Visits 1 and 2 can occur simultaneously if subject had index surgery more than 24 months prior to enrollment.
[b] Pre-op and Post-op, and 1 year, if available. If subject had a revision prior to signing ICF, do not collect any Patient-Reported Outcomes (PROs). If subject is within window for Visit 1 (Initial) and retrospective data is not available, radiographic data and PROs (KSS, EQ-5D-5L, SAPSS and FJS) can be collected prospectively.
[c] As appropriate.
[d] Query subjects for adverse events at each visit.

6.2 VISIT 1: INITIAL VISIT

NOTE: Any subject who provides informed consent, but fails to meet the required Inclusion/Exclusion criteria is considered to be a Screen Failure. Subject demographic CRF must be completed and the reason for screen failure specified on the End of Study CRF.

(For subjects whose surgery occurred 36 (± 12) months ago, this visit will be combined with Visit 2.)

Procedures to be completed at the Visit 1 (Initial):

1. Confirm ICF obtained.
2. Confirm subject meets inclusion/exclusion criteria.
3. Collect Demographics/Medical History.
4. Collect Operative/Discharge information.
5. Collect available *retrospective* radiographic data: latest preoperative (collected within 6 months prior to surgery), earliest postoperative (collected within 6 months after surgery), and 1-year (12-18 months). If subject is within window and retrospective data is not available, radiographic data can be collected prospectively.
    - Include weight-bearing anteroposterior (AP) and lateral standard x-rays.
6. Collect available *retrospective* PROs: latest preoperative (collected within 6 months prior to surgery), earliest postoperative (collected within 6 months after surgery), and 1-year (12-18 months). If subject is within window and retrospective data is not available, PROs can be collected prospectively.
    - KSS
    - EQ-5D-5L
    - SAPSS
    - FJS
7. Record any related Serious Adverse Event (SAE)/Adverse Device Effect (ADE)/Device Deficiency (DevD) since surgery per Section 9.
8. Determine implant disposition**:

    Subjects who were identified to have had a revision during screening should complete Visit 1 (Initial) procedures 1-5. Subjects with unilateral implants will complete Implant Disposition CRF and End of Study CRF and be terminated from the study; **do not collect any PROs (either retro or prospective) for these subjects.

    Subjects with bilateral JOURNEY UNI UKS implants who have had a single revision prior to the start of the study will complete an Implant Disposition CRF for the revised joint and only that joint will be terminated; the subject will remain in the study and the remaining implant will be followed per the protocol visit schedule.
9. Schedule 36-Month Visit, if appropriate.

6.3 VISIT 2: 36 (± 12) MONTHS

If this is the subject's first visit, complete Visit 1 (Initial) items 1-7

(For subjects whose surgery occurred 36 (± 12) months ago, this visit will be combined with Visit 1 [Initial].)

10. Perform weight-bearing AP and lateral standard x-rays.
11. Collect the following evaluations/questionnaires:
    - KSS
    - EQ-5D-5L
    - SAPSS
    - FJS

12. Determine implant disposition; complete CRF if appropriate.
13. Record any adverse events since last visit per Section 9.
14. Schedule 60-Month Visit, if appropriate.

6.4 VISIT 3: 60 (± 12) MONTHS

1. Perform weight-bearing AP and lateral standard x-rays.
2. Collect the following evaluations/questionnaires:
    - KSS
    - EQ-5D-5L
    - SAPSS
    - FJS
3. Determine implant disposition; complete Implant Disposition CRF
4. Record any adverse events since last visit per Section 9.
5. Complete End of Study: Subject Disposition.

6.5 UNSCHEDULED VISITS

Any unscheduled visits should be recorded in the CRF. The subject should be scheduled to return for the next scheduled study visit within the acceptable time window, if applicable.

6.5.1 Unscheduled Visit for SAE/ADE Reporting

All subjects (excluding those with revisions prior to enrollment) will have prospective 36- and 60-month visits that include an assessment for adverse events. If during phone contact or between visits, the subject is deemed symptomatic with pain, swelling, and/or concern about potential device-related AE, arrange for an unscheduled visit.

6.5.2 Unscheduled Visit for X-ray/PRO Reporting

X-rays and/or questionnaires/evaluations collected outside of those specifically listed in the visit schedule should be reported on applicable Unscheduled Visit CRF pages.

6.5.3 Missed Visit

If a subject fails to complete all assessments for a particular visit, complete a Missed Visit CRF.

7. Assessment Techniques

7.1 2011 KNEE SOCIETY SCORE

The Knee Society Knee Scoring System (KSS) is both physician and patient-derived. It includes versions to be administered preoperatively and postoperatively. It has an initial assessment of demographic details, including an expanded Charnley functional classification. The objective knee score, completed by the

surgeon, includes a visual analog scale (VAS) score of pain walking on level ground and on stairs or inclines, as well as an assessment of alignment, ligament stability, and Range of Motion (ROM), along with deductions for flexion contracture or extensor lag. Subjects then record their satisfaction, functional activities, and expectations. Given the diverse activity profiles of many contemporary subjects, the functional component of the score was improved to include a patient-specific survey, which evaluates features such as standard activities of daily living, patient-specific sports and recreational activities, patient satisfaction, and patient expectations[13].

7.2 The EuroQol Five Dimensions Questionnaire

The EuroQol Five Dimensions Questionnaire (EQ-5D-5L) is an instrument that derives a single index for Quality of Life (QoL) and has two sections. The first section consists of five questions covering the dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The second part consists of a 20-centimeter vertical VAS ranging from 0 to 100. It records the respondent's self-rated health where the endpoints are labeled 'Best imaginable health state' and 'Worst imaginable health state'.

This information can be used as a quantitative measure of health outcome as judged by the individual respondents[14]. EQ-5D-5L is completed by the subject on the day of his/her visit.

7.3 Self-Administered Patient Satisfaction Survey for Primary Hip and Knee Arthroplasty

The SAPSS is a 4-item self-administered questionnaire that asks subjects about their satisfaction levels after arthroplasty using a scale of Very Satisfied, Somewhat Satisfied, Somewhat Dissatisfied, and Very Dissatisfied. The SAPSS score will be reported as the percent of subjects selecting any of the scale choices. Additionally, how these percentages change over the course of the study will also be reported for each time point that the instrument was administered[15].

7.4 Forgotten Joint Score

The FJS will assess the subject's ability to forget the artificial joint in everyday life. Joint awareness can be simply defined as any unintended perception of a joint[16]. The FJS for an individual subject is rated on a scale of 1-100, where 100 is the best/max score.

7.5 Radiographic Assessments

Several radiographic views are required to adequately assess the component position, prosthesis-bone interface, and the knee alignment. Radiographic data will be recorded by the Investigator on the radiographic CRF. At Visit 1 (Initial), weight-bearing AP and lateral radiographs that were taken as standard of care at the clinical site, including preoperative, postoperative, and 1-year data, should be collected from the medical record.

At all visits, standard radiographs should include:

- a single view of the index joint in weight-bearing AP view
- a single view of the index joint in weight-bearing lateral view

Assessments to be made from preoperative radiographs will include:

- Mechanical alignment
- Presence of osteophytes

Assessments to be made from all postoperative radiographs will include:

- Presence of osteophytes
- Osteolysis
- Component orientation
- Radiolucencies
- Implant loosening
- Implant subsidence/migration
- Stress shielding
- Periprosthetic fracture
- Wear of the articulating surfaces of replacement components

8. Subject Completion and Disposition

8.1 Screening and Informed Consent

An IRB/EC waiver of informed consent for study participation should be requested for those subjects who have had a revision 12-48 months after surgery and are deceased or are lost to follow-up, per IRB/EC policy. If allowed, a retrospective data set will be collected on these subjects. A copy of the waiver of informed consent will be placed in the subject file.

Subjects who meet eligibility criteria and are alive, will be contacted and asked to provide Informed Consent prior to any retrospective or prospective data collection.

Consent must be obtained from all study subjects using an IRB/EC approved ICF according to ISO14155 guidelines, Good Clinical Practice (GCP) guidelines, and all applicable national regulations. The subject shall have sufficient opportunity to consider participation in the study; a subject cannot be led to believe that they are waiving his/her rights as a subject or the liability of the Sponsor or Investigator. Before conducting any study procedures or examinations, potential subjects must be informed of the purpose of the study. The potential risks and benefits known or that can be reasonably predicted or expected as described in the ICF will be explained to the subject in their native language.

The subject, will then read, sign, and date (or approve per IRB/IEC guidelines) the IRB/EC-approved ICF. Additionally, the individual who obtains consent from the subject will sign and date the ICF. The informed consent process will be documented in the subject's medical record and date of signed ICF recorded on the study Case Report Forms (CRFs). A copy of the signed informed consent document will be provided to the subject, a copy will be placed in the subject's medical record, with the original filed in the Investigator Site File.

The PI or delegated study research staff may then complete Visit 1 (Initial) with the subject.

If a subject refuses participation, no further information will be collected. Reason for exclusion should be noted on the Screening and Enrollment Log.

8.2 ENROLLED SUBJECT

Subject enrollment occurs when the ICF is signed by the subject and the site.

8.3 CONDITIONS FOR STUDY TERMINATION

All reasonable efforts should be made to retain the subjects for the duration of this study. An End of Study: Subject Disposition CRF needs to be completed for any subject that does not complete the study, to document the reason for termination.

8.3.1 Revision of the Study Device

If a unilateral implant subject has a revision of any device component, the subject will be exited from the study. If a subject has bilateral implants and has a revision on one side only, the subject will be maintained in the study and the remaining implant will continue to be followed per the protocol visit schedule.

Details concerning an implant revision will be recorded on the Implant Disposition CRF.

8.3.2 Screening Failure

Subjects that are screened and consented to participate in the study but later withdraw consent before Visit 2 will not count towards the estimated sample size; these subjects will be replaced.

8.3.3 Voluntary Withdrawal

Study participation is voluntary and subjects may withdraw at any point during the study without giving their reason for doing so. An End of Study: Subject Disposition CRF will be completed for all subjects who do not finish the study, documenting the reason for withdrawal.

8.3.4 Lost to Follow-Up

Some actively enrolled subjects will not return for follow-up exams. Study personnel must make a reasonable effort to contact the subject and document the following contact attempts prior to declaring a subject to be Lost To Follow-Up (LTFU): the subject has been contacted according to the site's policies, but no fewer than 3 documented attempts to contact the subject including at least 1 written. Copies of all attempts to reach the subjects per regular mail or email and/or the attempts to contact the subject via other means should be documented and that documentation should be kept with the subject's medical record. A subject will be considered LTFU if he/she does not appear for the scheduled study visit and study personnel are unable to make contact with the subject.

8.3.5 Study Termination by Investigator/Sponsor

The Investigator **may** withdraw subjects from the study for many reasons, including but not limited to the following:

- subject noncompliance to study schedule
- subject LTFU

The Investigator **should** withdraw subjects from the study:

- if any component of the original hardware is revised/exchanged, in the case of a subject with a unilateral implant. (Subjects with bilateral implants who experience a single revision should stay in the study with the remaining implant.)
- if the Investigator or the Sponsor stop the study for any reason

For each case, information will be obtained on the End of Study: Subject Disposition CRF, detailing circumstances leading to the withdrawal.

8.3.6 Pregnancy

If during the course of the study a subject becomes pregnant, study procedures that are contraindicated during pregnancy and/or lactation (e.g. x-rays) will not be required; however, the subject will continue to be followed for study visits and information will be collected regarding the outcome of the birth.

8.3.7 Study Site Discontinuation

A specific study site in this multicenter study may also warrant termination under the following conditions:

- noncompliance to GCP or protocol
- failure to enroll subjects
- protocol deviations
- inaccurate or incomplete data
- unsafe or unethical practices
- safety or performance considerations
- investigator involuntarily discontinues participation in the study

9. Safety Reporting

All AE related to the study device or procedure including ADE, Serious Adverse Device Effect (SADE), Unanticipated Serious Adverse Device Effect (USADE), and DevD occurring from the time of study device implantation must be collected and reported until the time of revision surgery (if applicable). If the event is known to have been previously reported to Smith & Nephew, this must be noted on the CRF and reported as described below.

All AEs occurring after study enrollment regardless of causality must be recorded on the appropriate CRF and reported to the Sponsor and IRB/EC in accordance with their policy.

9.1 DEFINITIONS FOR SAFETY REPORTING

9.1.1 Adverse Event

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, whether or not related to the study device[17].

This definition includes:

- events related to the study device
- events related to the procedures involved
- a worsening of any conditions previously recorded as part of the medical history assessment

9.1.2 Serious Adverse Event

An SAE is an adverse event that[17]:

- led to death,
- led to serious deterioration in the health of the subject, that either resulted in:
    1) a life-threatening illness or injury, or
    2) a permanent impairment of a body structure or a body function, or
    3) inpatient or prolonged hospitalization, or
    4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
- led to fetal distress, fetal death or a congenital abnormality or birth defect.

Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered an SAE.

9.1.3 Adverse Device Effect

An ADE is an adverse event related to the use of the study device[17].

This definition includes:

- AE resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the study device
- any event resulting from use error or from intentional misuse of the study device.

9.1.4 Serious Adverse Device Effect

A SADE is an ADE that has resulted in any of the consequences characteristic of an SAE[17].

9.1.5 Unanticipated Serious Adverse Device Effect

A USADE is a SADE which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report or the protocol[17,18].

9.1.6 Device Deficiency

A DevD is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. DevD include malfunctions, use errors, and inadequate labeling.

For this study, DevD should be reported when they concern any component of the study device as well as its packaging and tools that need to be used during implantation according to the Instructions for Use (AF

9.1.7 Device Revisions

A Study Implant Disposition CRF will be completed in addition to the AE Form, to document in detail revisions of any of the components of the study device.

9.2 SAFETY: INVESTIGATOR'S RESPONSIBILITIES

Investigators shall record SAE, ADE, and observed DevD, together with an assessment, in the subject's source data.

Investigators are responsible for documenting SAE, ADE, and DevD on the appropriate CRF and submitting them to the Sponsor according to the timelines described.

At each contact with the subject, the Investigator must seek information on AE by specific questioning and, as appropriate, by assessment of the subject. AE must be recorded in standard English medical terminology.

Unresolved AE should be followed by the Investigator until the events are resolved, the subject is LTFU or through to the end of the study, whichever timing occurs first. Unresolved AE at the end of the subject's participation will be monitored by the Investigator as part of the site's normal standard of care.

The Investigator will categorize AE as mild, moderate or severe based on the following definitions:

- Mild: the subject is aware of the sign or symptom, but finds it easily tolerated. The event is of little concern to the subject and/or little clinical significance. The event is not expected to have any effect on the subject's overall health or well-being.
- Moderate: the subject has discomfort enough to cause interference with or change in usual activities. The event is of some concern to the subject's health or well-being and may require medical intervention and/or close follow-up.
- Severe: the AE interferes considerably with the subject's usual activities. The event is of definite concern to the subject and/or poses substantial risk to the subject's health or well-being. The event is likely to require medical intervention and/or close follow-up and may be incapacitating or life-threatening. Hospitalization and treatment may be required.

The Investigator is responsible for describing the relationship of the AE to the study device/procedure based on the following definitions:

- Unrelated: the event is clearly not related to the study device or procedure

- Possible: the event may or may not be related to the study device or procedure. A relationship cannot be ruled out.
- Definite: the event is clearly related to the study device or procedure.

9.3 TIMELINES FOR SUBMISSION OF SAFETY INFORMATION

The timelines begin when the Investigator becomes aware of the event.

The Investigator will report to the Sponsor:

- As soon as possible, but no greater than **24 hours upon becoming aware of the event, SAE, SADE*, USADE and DevD that could have led to a SADE**:
    - if suitable action had not been taken
    - if intervention had not been made, or
    - if circumstances had been less fortunate
- **Revisions**, **within 24 hours upon becoming aware of the event.** Sponsor will provide an explant retrieval kit on becoming aware of a revision and ask the Investigator to return any revised components for retrieval analysis.

Investigators may also be asked to supply the Sponsor, upon Sponsor's request, with any additional information related to the safety reporting of a particular event.

* Retrospective SADE do not require reporting within 24 hours but should be reported promptly, if a product complaint was not previously submitted to Smith & Nephew Product Complaints

The PI will be responsible for reporting to the IRB/EC and to the regulatory authorities, SAE, SADE, and DevD that could have led to a SADE, as required by the local and national regulations.

9.3.1 Adverse Events Ongoing at Study Discontinuation

Unresolved AE related to a study procedure or Smith & Nephew device should be followed by the Investigator until the events are resolved or to the end of the study, whichever occurs first. Unresolved AEs at the end of study participation should be monitored by the Investigator as part of the site's normal standard of care. If still ongoing, these events should be listed as ongoing on the CRF.

9.4 SAFETY REPORTING: SPONSOR'S RESPONSIBILITIES

Sponsor will provide progress reports on safety events to the Investigator to report to the IRB/EC as required. In the case of multicenter studies, Sponsor will inform all Investigators in writing of all SADE that were reported by all sites throughout the clinical investigation and based on perceived risk.

The Sponsor will also, in the case of SADE and DevD that could have led to SADE, determine whether the risk analysis needs to be updated and assess whether corrective or preventive action is required.

10. Statistical Procedures

Smith & Nephew Global Biostatistics Department will conduct statistical analysis. Unless otherwise stated, all significance tests and hypothesis testing will be two-sided and performed at the 5% significance level.

Where data summaries are specified, categorical and ordinal variables will be summarized using frequency distributions which will detail the number and percentage of subjects which fall into each category. Continuous variables will be summarized using the following summary statistics: mean, median, standard deviation, minimum and maximum values, and number of observations.

In formal analyses, resulting P-values will be quoted and 95% two-sided confidence intervals generated where appropriate. Prognostic factors will be adjusted for, if necessary.

For survivorship analyses, revisions are defined as revision for any reason.

All analyses will be performed in Statistical Analysis System (SAS) v9.4, or later.

10.1 Sample Size Calculation

This study will screen and consent until 147 knees from approximately 10 sites have been enrolled.

The study is intended to test for non-inferiority in the percentage of revision-free survival at 5 years recorded during the study compared to existing literature. The 2015 AOA Annual Report records the revision-free survival for unicompartmental knees at 5 years as 91.7%.

Using a non-inferiority margin of 8%, a sample size of 125 subjects will provide at least 80% power at the 5% significance level using exact binomial methods. To allow for a 15% attrition and drop-out rate, a total of 147 knees will be enrolled.

Subjects that are screened and consented to participate in the study but later withdraw consent before Visit 2 will not count towards the estimated sample size; these subjects will be replaced.

10.2 Missing Data

The methods used to handle missing or incomplete data for the effectiveness and safety measures will be detailed in the Statistical Analysis Plan (SAP).

10.3 Analysis Populations

- Safety (SAF) population - All subjects who have received study treatment. This population will be used for safety analysis.
- Intent to Treat (ITT) population: All subjects who received study treatment and have any post-baseline data. This population will be used for the primary analysis of all effectiveness endpoints

- Per protocol (PP) population - Includes all subjects in the ITT population who do not deviate significantly from the protocol and who meet the inclusion/exclusion criteria of the study. This population will be used to as secondary analysis for effectiveness endpoints.

10.4 EFFECTIVENESS ANALYSIS

Analysis of the primary endpoint is detailed below; further analyses will be detailed in the SAP.

The primary endpoint is 5-year revision-free survival. The proportion of subjects who do not have implant failure by the 5-year time point will be presented along with the 95% confidence interval for the proportion, to be calculated using exact binomial methods.

Non-inferiority will be assessed using a margin of 8% against the percentage of revision-free survival at 5 years recorded during the study, compared to existing literature. The 2015 AOA Annual Report records the revision-free survival for unicompartmental knees at 5 years as 91.7%.

10.5 SAFETY ANALYSES

All safety analyses and summaries will be conducted using the Safety Population. Device-related AE and SAE will be summarized. Further details of these summaries will be included in the SAP.

11. Ethical Considerations

11.1 ETHICAL APPROVAL

In accordance with the Declaration of Helsinki and local regulations of the participating countries, sites must gain written IRB/EC approval prior to enrolling research participants in the study.

11.2 PROTOCOL AMENDMENTS

Neither the Investigator nor the Sponsor will modify this protocol without mutual agreement. After agreement to initiate the modification - in the form of a protocol amendment - the Investigator agrees not to implement this modification until instructed to do so by the Sponsor. It will be necessary to obtain IRB/EC approval prior to implementation of any change in the protocol that may affect the scientific soundness or the rights, safety, or welfare of the subjects involved. Notification shall be submitted to the IRB/EC by the Investigator.

11.3 RISK – BENEFIT ANALYSIS

11.3.1 Study Related Risks

As a result of participating in the study, there could be a risk of loss of protected subject information confidentiality. All applicable confidentiality standards and data protection and privacy laws will be followed by the Sponsor to ensure that data collected is handled in confidence. Data will be coded and handled only by appropriately qualified and authorized personnel.

11.3.2 Study Related Benefits

Because the surgery and all the follow-up visits are the same as if the subject did not participate in this study, there are no additional medical benefits associated with participating in this study. The information gained from this study may help improve the treatment of people that need to undergo UKA.

12. Monitoring Procedures

12.1 Source Documentation

Investigators are responsible for obtaining and maintaining complete subject health information in the medical record for each subject (source documents). Examples of source documents are hospital records, clinic and office charts, memoranda, dispensing records, subject questionnaires, clinic evaluation transcriptions, operative notes, x-rays, radiology reports, blood collection reports and shipment records, and research subject files.

CRF may be used as source documents if they represent data collected for the study and are the location that data is initially recorded. For this study only PROs (KSS, FJS, SAPSS, EQ-5D-5L) may be completed on CRFs directly.

The PI will ensure that clinical records are clearly marked to indicate that the subject is enrolled in a particular clinical study and if they completed per protocol or discontinued early and the reason.

12.2 Direct Access

This study will be monitored by the Sponsor or a qualified person designated by the Sponsor. This qualified person could be an employee of the Sponsor or of a contract research organization (Sponsor's agent).

The Investigator will provide Sponsor, Sponsor's agents, IRB/EC and regulatory agencies with direct access to all source data/documents to permit study-related monitoring, audits, IRB/EC review, and regulatory inspections.

12.3 Site Qualification Visit

A site qualification visit may be performed by the Sponsor prior to the execution of a clinical agreement to ensure that all Investigators have the appropriate training, staff, facilities, and resources to adequately conduct the study.

12.4 Site Initiation Visit

A site initiation visit to provide training on the specifics of the study, site obligations and expectations of study conduct will be performed by the Sponsor. No screening or other study procedures may be performed prior to the execution of the Clinical Study Agreement and documented IRB/EC approval.

12.5 INTERIM MONITORING VISITS

The Sponsor or its designee will conduct the appropriate site visits at the appropriate intervals. The clinical investigation will be monitored to ensure that the rights and well-being of the subjects are protected; the reported data are accurate, complete, and verifiable from the source documents; and the study is conducted in compliance with the currently approved protocol, with GCP regulations, and with applicable regulatory requirements. Detailed monitoring requirements will be documented within the Clinical Monitoring Plan for this study.

12.6 CLOSEOUT VISIT

The Sponsor or its designee will conduct a study close-out visit. During study close-out, the monitor will review investigator files to ensure required documents and records are on file, confirm the disposition of any other ancillary items used for the study, and review regulatory requirements regarding records retention and IRB/EC reporting requirements.

12.7 SPONSOR AUDITS AND REGULATORY INSPECTION

Quality Assurance auditors, whether an employee of the Sponsor or its designee may evaluate study conduct at the study sites. These parties must have access to any and all study reports and source documentation, regardless of location and format.

12.8 DATA HANDLING AND RECORD KEEPING REQUIREMENTS

The CRF will be supplied by the Sponsor. Subjects will be identified by a subject identification and subject code. Only the Investigative site will have the key to identify individual subjects. The Investigator is responsible for the timely and accurate completion of the CRF. All documents related to the study must be securely archived at the study site or in a central archive.

Data required according to this protocol are to be recorded on the CRF when available. Once a subject is enrolled, completed CRF should be sent to the Sponsor, either by fax or by e-mail, as soon as possible upon completion of the CRF.

12.9 DATA RECORDING AND RECORD RETENTION

Clinical research records shall be stored in a manner that ensures privacy, confidentiality, security, and accessibility of the records both during and after the conduct of the study. The Investigator/Institution will take measures to prevent the accidental or premature destruction of those documents. The Investigator must retain essential study documents for at least 2 years after the date the study is terminated. If the Investigator needs to dispose of the documents, the Sponsor should be contacted for approval prior to disposal or destruction. For discontinued product, the essential documents will be retained until at least 2 years have elapsed since the formal discontinuation (via notification of the Food and Drug Administration (FDA) or other regulatory agency) of clinical development of the investigational product. The investigator will retain these documents for a longer period if required by the applicable local laws.

If the responsible investigator retires, relocates, or withdraws from responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. The Sponsor must be notified in writing of the name and address of the new custodian. Under no circumstance shall the Investigator relocate or dispose of any study documents before having obtained written approval from the Sponsor.

13. Deviations from Protocol

A protocol deviation is an instance of failure, intentionally or unintentionally, to follow the requirements of the protocol. Protocol deviations include but are not limited to deviations from inclusion/exclusion criteria, endpoint variable criteria, study visits outside the window, and GCP guidelines.

13.1 PROTOCOL DEVIATION REPORTING REQUIREMENTS

Deviations must be reported to the Sponsor as soon as reasonably possible.

When protocol deviations affect the scientific soundness of the study or the rights, safety, or welfare of the study subjects, the Investigator must also report protocol deviations to the IRB/EC. It is the responsibility of the PI to inform the IRB/EC of the incident, per local requirements. The local IRB/EC should be consulted on protocol deviation reporting requirements.

Investigators and all study staff (staff at site and at Sponsor) are responsible for ensuring adherence to study protocol. During the monitoring visits, the Sponsor representative will review all deviations with the Investigator. If a deviation is discovered outside of a monitoring visit, it should be evaluated via phone, email or letter. Appropriate measures to address the occurrence, additional monitoring visits, or audit of the study should be taken, which may include defining and implementing a Corrective and Preventive Action.

14. Publication Policy

The preparation and submission for publication of manuscripts containing the study results shall be in accordance with a process determined by the Clinical Trial Agreements between the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to the Health Insurance Portability and Accountability Act of 1996.

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17. ISO14155:2011 Clinical investigation of medical devices for human subjects – good clinical practice.
18. Code of Federal Regulations Title 21, Subchapter H Medical Devices, Part 812 Investigational Device Exemptions.

Appendix I. List of Part Numbers

P/N	Description	Size/Leg
JOURNEY UNI femoral components		
7142-2341	JOURNEY UNI OXINIUM femoral	Sz 1 LM/RL
7142-2342	JOURNEY UNI OXINIUM femoral	Sz 2 LM/RL
7142-2343	JOURNEY UNI OXINIUM femoral	Sz 3 LM/RL
7142-2344	JOURNEY UNI OXINIUM femoral	Sz 4 LM/RL
7142-2345	JOURNEY UNI OXINIUM femoral	Sz 5 LM/RL
7142-2346	JOURNEY UNI OXINIUM femoral	Sz 6 LM/RL
7142-2347	JOURNEY UNI OXINIUM femoral	Sz 7 LM/RL
7142-2351	JOURNEY UNI OXINIUM femoral	Sz 1 RM/LL
7142-2352	JOURNEY UNI OXINIUM femoral	Sz 2 RM/LL
7142-2353	JOURNEY UNI OXINIUM femoral	Sz 3 RM/LL
7142-2354	JOURNEY UNI OXINIUM femoral	Sz 4 RM/LL
7142-2355	JOURNEY UNI OXINIUM femoral	Sz 5 RM/LL
7142-2356	JOURNEY UNI OXINIUM femoral	Sz 6 RM/LL
7142-2357	JOURNEY UNI OXINIUM femoral	Sz 7 RM/LL
7142-2361	JOURNEY UNI COCR FB femoral	Sz 1 LM/RL
7142-2362	JOURNEY UNI COCR FB femoral	Sz 2 LM/RL
7142-2363	JOURNEY UNI COCR FB femoral	Sz 3 LM/RL
7142-2364	JOURNEY UNI COCR FB femoral	Sz 4 LM/RL
7142-2365	JOURNEY UNI COCR FB femoral	Sz 5 LM/RL
7142-2366	JOURNEY UNI COCR FB femoral	Sz 6 LM/RL
7142-2367	JOURNEY UNI COCR FB femoral	Sz 7 LM/RL
7142-2371	JOURNEY UNI COCR FB femoral	Sz 1 RM/LL
7142-2372	JOURNEY UNI COCR FB femoral	Sz 2 RM/LL
7142-2373	JOURNEY UNI COCR FB femoral	Sz 3 RM/LL
7142-2374	JOURNEY UNI COCR FB femoral	Sz 4 RM/LL
7142-2375	JOURNEY UNI COCR FB femoral	Sz 5 RM/LL
7142-2376	JOURNEY UNI COCR FB femoral	Sz 6 RM/LL
7142-2377	JOURNEY UNI COCR FB femoral	Sz 7 RM/LL
JOURNEY UNI tibial baseplates		
7142-2421	JOURNEY UNI tibial base	Sz 1 LM/RL
7142-2422	JOURNEY UNI tibial base	Sz 2 LM/RL
7142-2423	JOURNEY UNI tibial base	Sz 3 LM/RL
7142-2424	JOURNEY UNI tibial base	Sz 4 LM/RL
7142-2425	JOURNEY UNI tibial base	Sz 5 LM/RL
7142-2426	JOURNEY UNI tibial base	Sz 6 LM/RL
7142-2431	JOURNEY UNI tibial base	Sz 1 RM/LL
7142-2432	JOURNEY UNI tibial base	Sz 2 RM/LL

P/N	Description	Size/Leg
7142-2433	JOURNEY UNI tibial base	Sz 3 RM/LL
7142-2434	JOURNEY UNI tibial base	Sz 4 RM/LL
7142-2435	JOURNEY UNI tibial base	Sz 5 RM/LL
7142-2436	JOURNEY UNI tibial base	Sz 6 RM/LL
JOURNEY UNI tibial inserts		
7142-2241	JOURNEY UNI tibial insert	Sz 1-2 LM/RL 8mm
7142-2242	JOURNEY UNI tibial insert	Sz 1-2 LM/RL 9mm
7142-2243	JOURNEY UNI tibial insert	Sz 1-2 LM/RL 10mm
7142-2244	JOURNEY UNI tibial insert	Sz 1-2 LM/RL 11mm
7142-2245	JOURNEY UNI tibial insert	Sz 1-2 RM/LL 8mm
7142-2246	JOURNEY UNI tibial insert	Sz 1-2 RM/LL 9mm
7142-2247	JOURNEY UNI tibial insert	Sz 1-2 RM/LL 10mm
7142-2248	JOURNEY UNI tibial insert	Sz 1-2 RM/LL 11mm
7142-2251	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 8mm
7142-2252	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 9mm
7142-2253	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 10mm
7142-2254	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 11mm
7142-2255	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 8mm
7142-2256	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 9mm
7142-2257	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 10mm
7142-2258	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 11mm
7142-2261	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 8mm
7142-2262	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 9mm
7142-2263	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 10mm
7142-2264	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 11mm
7142-2265	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 8mm
7142-2266	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 9mm
7142-2267	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 10mm
7142-2268	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 11mm
7193-3296	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 12mm*
7193-3297	JOURNEY UNI tibial insert	Sz 3-4 LM/RL 14mm*
7193-3298	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 12mm*
7193-3299	JOURNEY UNI tibial insert	Sz 3-4 RM/LL 14mm*
7193-3300	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 12mm*
7193-3301	JOURNEY UNI tibial insert	Sz 5-6 LM/RL 14mm*
7193-3302	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 12mm*
7193-3303	JOURNEY UNI tibial insert	Sz 5-6 RM/LL 12mm*
JOURNEY UNI all-poly tibial inserts		
7142-2271	JOURNEY UNI all-poly tibial	Sz 1 LM/RL 8mm
7142-2272	JOURNEY UNI all-poly tibial	Sz 1 LM/RL 9mm
7142-2273	JOURNEY UNI all-poly tibial	Sz 1 LM/RL 10mm

P/N	Description	Size/Leg
7142-2274	JOURNEY UNI all-poly tibial	Sz 1 LM/RL 11mm
7142-2275	JOURNEY UNI all-poly tibial	Sz 1 RM/LL 8mm
7142-2276	JOURNEY UNI all-poly tibial	Sz 1 RM/LL 9mm
7142-2277	JOURNEY UNI all-poly tibial	Sz 1 RM/LL 10mm
7142-2278	JOURNEY UNI all-poly tibial	Sz 1 RM/LL 11mm
7142-2281	JOURNEY UNI all-poly tibial	Sz 2 LM/RL 8mm
7142-2282	JOURNEY UNI all-poly tibial	Sz 2 LM/RL 9mm
7142-2283	JOURNEY UNI all-poly tibial	Sz 2 LM/RL 10mm
7142-2284	JOURNEY UNI all-poly tibial	Sz 2 LM/RL 11mm
7142-2285	JOURNEY UNI all-poly tibial	Sz 2 RM/LL 8mm
7142-2286	JOURNEY UNI all-poly tibial	Sz 2 RM/LL 9mm
7142-2287	JOURNEY UNI all-poly tibial	Sz 2 RM/LL 10mm
7142-2288	JOURNEY UNI all-poly tibial	Sz 2 RM/LL 11mm
7142-2291	JOURNEY UNI all-poly tibial	Sz 3 LM/RL 8mm
7142-2292	JOURNEY UNI all-poly tibial	Sz 3 LM/RL 9mm
7142-2293	JOURNEY UNI all-poly tibial	Sz 3 LM/RL 10mm
7142-2294	JOURNEY UNI all-poly tibial	Sz 3 LM/RL 11mm
7142-2295	JOURNEY UNI all-poly tibial	Sz 3 RM/LL 8mm
7142-2296	JOURNEY UNI all-poly tibial	Sz 3 RM/LL 9mm
7142-2297	JOURNEY UNI all-poly tibial	Sz 3 RM/LL 10mm
7142-2298	JOURNEY UNI all-poly tibial	Sz 3 RM/LL 11mm
7142-2301	JOURNEY UNI all-poly tibial	Sz 4 LM/RL 8mm
7142-2302	JOURNEY UNI all-poly tibial	Sz 4 LM/RL 9mm
7142-2303	JOURNEY UNI all-poly tibial	Sz 4 LM/RL 10mm
7142-2304	JOURNEY UNI all-poly tibial	Sz 4 LM/RL 11mm
7142-2305	JOURNEY UNI all-poly tibial	Sz 4 RM/LL 8mm
7142-2306	JOURNEY UNI all-poly tibial	Sz 4 RM/LL 9mm
7142-2307	JOURNEY UNI all-poly tibial	Sz 4 RM/LL 10mm
7142-2308	JOURNEY UNI all-poly tibial	Sz 4 RM/LL 11mm
7142-2311	JOURNEY UNI all-poly tibial	Sz 5 LM/RL 8mm
7142-2312	JOURNEY UNI all-poly tibial	Sz 5 LM/RL 9mm
7142-2313	JOURNEY UNI all-poly tibial	Sz 5 LM/RL 10mm
7142-2314	JOURNEY UNI all-poly tibial	Sz 5 LM/RL 11mm
7142-2315	JOURNEY UNI all-poly tibial	Sz 5 RM/LL 8mm
7142-2316	JOURNEY UNI all-poly tibial	Sz 5 RM/LL 9mm
7142-2317	JOURNEY UNI all-poly tibial	Sz 5 RM/LL 10mm
7142-2318	JOURNEY UNI all-poly tibial	Sz 5 RM/LL 11mm
7142-2321	JOURNEY UNI all-poly tibial	Sz 6 LM/RL 8mm
7142-2322	JOURNEY UNI all-poly tibial	Sz 6 LM/RL 9mm
7142-2333	JOURNEY UNI all-poly tibial	Sz 6 LM/RL 10mm
7142-2334	JOURNEY UNI all-poly tibial	Sz 6 LM/RL 11mm

P/N	Description	Size/Leg
7142-2335	JOURNEY UNI all-poly tibial	Sz 6 RM/LL 8mm
7142-2336	JOURNEY UNI all-poly tibial	Sz 6 RM/LL 9mm
7142-2337	JOURNEY UNI all-poly tibial	Sz 6 RM/LL 10mm
7142-2338	JOURNEY UNI all-poly tibial	Sz 6 RM/LL 11mm
7142-2401	JOURNEY Uni all-poly tibial	Sz 1 LM/RL 7mm
7142-2402	JOURNEY Uni all-poly tibial	Sz 2 LM/RL 7mm
7142-2403	JOURNEY Uni all-poly tibial	Sz 3 LM/RL 7mm
7142-2404	JOURNEY® Uni all-poly tibial	Sz 4 LM/RL 7mm
7142-2405	JOURNEY Uni all-poly tibial	Sz 5 LM/RL 7mm
7142-2406	JOURNEY Uni all-poly tibial	Sz 6 LM/RL 7mm
7142-2407	JOURNEY Uni all-poly tibial	Sz 1 RM/LL 7mm
7142-2408	JOURNEY Uni all-poly tibial	Sz 2 RM/LL 7mm
7142-2409	JOURNEY Uni all-poly tibial	Sz 3 RM/LL 7mm
7142-2410	JOURNEY Uni all-poly tibial	Sz 4 RM/LL 7mm
7142-2411	JOURNEY Uni all-poly tibial	Sz 5 RM/LL 7mm
7142-2412	JOURNEY Uni all-poly tibial	Sz 6 RM/LL 7mm

*12mm and 14mm inserts are only available through InVentures

Addendum 1. Protocol Revision History

Version Date: 12 September 2017
Original Version Number: 1.0

Version Date: 07 December 2017
Version Number: 2.0
Summary of Revision(s) Made: Administrative changes only
Synopsis:
Study Device: tibia insert changed to tibial insert
Inclusion Criteria: tibial base plate changed to tibial baseplate; tibia insert changed to tibial insert
Section 4: Journey UNI Titanium 6Al-4V alloy or ultra-high molecular weight polyethylene (UHMWPE) "tibial components" changed to "tibial baseplate"
Section 6.3 Visit 2
Item 4. "related" deleted from sentence: Record any related SAE/ADE/DevD since last visit per Section 9.

Version Date: 15 April 2018
Version Number: 3
Summary of Revision(s) Made:
Overall updated text to collect all AEs not just device related.
Section 3 Study Design: Deleted text -who have provided a signed study informed consent form (ICF) for the collection of their data (see Section 8.1). Added text with the exception of Patient-Reported Outcomes (PROs) per section 12.1.
Section 3 Study Design: Deleted text -A maximum of 30 subjects may be enrolled from a single site.
Section 6.2 #8 Determine implant disposition**:
**Subjects who have had a revision within 24 months of the surgery changed to
**Subjects who were identified to of had a revision during screening
Section 8.1 Screening and Informed Consent new text added for clarification.
An IRB/EC waiver of informed consent for study participation should be requested for those subjects who have had a revision 12-48 months after surgery and are deceased or are lost to follow-up, per IRB/EC policy. If allowed, a retrospective data set will be collected on these subjects. A copy of the waiver of informed consent will be placed in the subject file.
Subjects who meet eligibility criteria and are alive, will be contacted and asked to provide Informed Consent prior to any retrospective or prospective data collection.
The informed consent process will be documented in the subject's medical record and date of signed ICF recorded on the study Case Report Forms (CRFs).
If a subject refuses participation, no further information will be collected. Reason for exclusion should be noted on the Screening and Enrollment Log.
Remove text referring to LAR, "or his/her legally authorized representative,"
(see below for difficulties with reading and writing).
If the subject is unable to read, the ICF and associated study information may be read aloud to the subject in the presence of an independent (i.e. not associated with the investigative site) witness. If possible the subject shall sign and personally date the ICF. Where this is not possible, due to difficulties in writing, the subject shall provide verbal consent to participate in the study in accordance with the site's IRB/EC policy.
Section 12.1 add text For this study only PROs (KSS, FJS, SAPSS, EQ-5D) may be completed on CRFs directly.

Version Date: 18 June 2019
Version Number: 4
Summary of Revision(s) Made:
Overall clarified Visit 1 (Initial)
Overall fixed typos for PRO**s**, EQ-5D-**5L,** to **have** had
Added Principal Investigator Signature Page and Sponsor Approval Page
Table 6.1-1 footer b

Pre-op and Post-op, and 1 year, if available. If subject had a revision **prior to signing ICF**, do not collect any Patient-Reported Outcomes (PROs). If subject is within window for Visit 1 (Initial) and retrospective data is not available, radiographic data and PROs (KSS, EQ-5D-5L, SAPSS and FJS) can be collected prospectively.

Section 6.2 #5 If subject is within window and retrospective data is not available, radiographic data can be collected prospectively.
Section 6.2 #6 If subject is within window and retrospective data is not available, PROs can be collected prospectively.

Version Date: 14 April 2020
Version Number: 5
Summary of Revision(s) Made:
Modified sample size from 147 subjects to 147 knees
Updated the length of study statement.
Clarified the 1 year study window.