Clinical, Radiographic and Patient-reported Outcomes Associated with the Use of the Navio® Robotic-assisted Surgical System in Total Knee Arthroplasty

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Study Product Name:	Navio® Robotic-assisted Surgical System
Sponsor:	Smith & Nephew, Inc. 1450 E. Brooks Road Memphis, TN 38116 US

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ABBREVIATIONS & DEFINITIONS

AE	Adverse Event
ADE	Adverse Device Effect
AP	Anteroposterior
CAPA	Corrective and Preventive Action
CRO	Contract Research Organization
CRF	Case Report Form
EC	Ethics Committee
EQ-5D	EuroQuol 5D
FDA	Food and Drug Administration
FU	Follow-Up
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IRB	Institutional Review Board
ITT	Intention to Treat Population
KSS	Knee Society Score
PI	Principal Investigator
PP	Per-protocol Population
QoL	Quality of life
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
TKA	Total Knee Arthroplasty
USADE	Unanticipated Serious Adverse Device Effect

Protocol Synopsis:

Title of Study:	Clinical, Radiographic, and Patient-reported Outcomes associated with the use of the Navio◇ Robotic-assisted Surgical System in Total Knee Arthroplasty
Study Type:	Evidence Generation
Study Device:	Navio◇ Robotic-assisted Surgical System
Study Purpose:	To demonstrate superior accuracy with the Navio◇ Robotic-assisted Surgical System in achieving desired post-operative mechanical alignment, compared to TKA procedures using standard instruments, as well as to document clinical and patient-reported outcomes in subjects receiving TKA with the Navio◇ system.
Study Design:	Multicenter, prospective single-arm cohort study with historical control.
Primary Endpoint:	Post-operative Mechanical Alignment (percentage of subjects achieving target alignment, defined as $\pm 3^{\circ}$ from target) at one month post-operative.
Secondary Endpoints:	• Implant survival rate from baseline to 2 year end of study visit. • Knee Society Score 2011 • Quality of Life (EQ-5D) 5L • Forgotten Joint Score (FJS) • Hospital Length of Stay • Operative Time • Radiographic Assessments
Safety Endpoints	The number of occurrences and the frequency of subjects reporting: • adverse events (AE) • serious adverse events (SAE) • adverse device effects (ADE) • serious adverse device effects (SADE) • unanticipated serious adverse • device effects (USADE) • device deficiencies (DevD)
Length of Study:	Approximately 3 years • 1 year for enrollment and 2 years for follow-up
Number of Sites:	Approximately 6 sites
Sample Size:	120 subjects
Inclusion Criteria:	1. Subject requires primary total knee arthroplasty with the Journey II BCS or Cruciate-Retraining (CR) Systems due to degenerative joint disease

	(primary diagnosis of osteoarthritis, post-traumatic arthritis, avascular necrosis, or rheumatoid arthritis). 2. Subject was considered skeletally mature at the time of implantation (at least 18 years or older). 3. Subject agrees to consent to and to follow the study visit schedule (as defined in the study protocol and informed consent form) by signing the IRB/EC approved informed consent form. 4. Subject plans to be available through two (2) years postoperative follow-up.
Exclusion Criteria:	1. Subject has BMI ≥ 40. 2. Subject has condition(s) that may interfere with the TKA survival or outcome (i.e., Paget's or Charcot's disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease, or an active, local infection). 3. Subject is deemed by investigator to require a constrained or deep dish tibial insert. 4. Subject has inadequate bone stock to support the device (severe osteopenia, history of severe osteoporosis, or severe osteopenia). 5. Subject has mental or neurologic condition(s) that may pre-empt the ability or willingness to restrict activities. 6. Subject is 80 years of age or older. 7. Subject is a prisoner or impending incarceration.

1. BACKGROUND AND STUDY RATIONALE

1.1. Background

Total Knee Arthroplasty (TKA) has become an effective and reliable treatment for arthritis of the knee (1). TKA is associated with low morbidity and mortality, and its effectiveness in reducing joint pain and improving range of motion is well established. In 2014, over 750,000 knee replacements were performed in the US (2).

A significant innovation in TKA has been the introduction of computer navigation and robotic-assisted surgery (3). One such technology is the Navio◇ Robotic-assisted Surgical System. This system is a semi-autonomous image-free system. During the surgery, the surgeon maps the condylar landmarks and determines alignment indices to define the volume and orientation of bone to be removed. The tools to remove the bone and place the implants are controlled and manipulated by the surgeon with the guidance of a 3-dimensional digital map of the surgical surface.

Originally the Navio◇ system was launched for use in unicondylar knee replacement only. To date, there have been over 1000 unicondylar knee replacement surgeries using the system. In 2017, Smith & Nephew Inc. expanded the indications for the Navio◇ system to include TKA. The purpose of this multicenter, prospective study is to evaluate outcomes associated with this new indication.

1.2. Study Rationale

The purpose of this study is to demonstrate superior accuracy with the Navio◇ Robotic-assisted Surgical System in achieving desired post-operative mechanical alignment, compared to TKA procedures using standard instruments. An additional study purpose is to document clinical and patient-reported outcomes in subjects receiving TKA with the Navio◇ system.

2. STUDY OBJECTIVES

2.1. Primary Objective

The primary objective of this study is to demonstrate the superiority of the use of the Navio◇ Robotic-assisted Surgical System in the implantation of the JOURNEY◇ II BCS or CR Systems in achieving post-operative mechanical alignment within ±3° of target, as compared to TKA procedures using standard instruments.

2.2. Secondary Objectives

Secondary objectives of this study include the generation of safety, performance, and health economic evidence supporting the use of the Navio◇ Robotic-assisted Surgical System in TKA procedures, per the endpoints listed below.

3. STUDY ENDPOINTS

3.1. Primary Endpoint

Post-operative Mechanical Alignment (the proportion of subjects achieving post-operative mechanical alignment, defined as ±3° from target) at the 1 month study visit.

3.2. Secondary Endpoints

The following assessments will be collected at each follow up visit, as described in Section 7.1, Table 1, Schedule of Events.

- Implant survival rate from baseline to 2 year end of study visit.
- Knee Society Score 2011
- Quality of Life (EQ-5D) 5L
- Forgotten Joint Score (FJS)
- Hospital Length of Stay
- Operative Time
- Radiographic Assessments

3.3. Safety Endpoints

The number of occurrences and the frequency of subjects reporting: adverse events (AE), serious adverse events (SAE), adverse device effects (ADE), serious adverse device effects (SADE), unanticipated serious adverse device effects (USADE), and device deficiencies (DevD).

4. Study Design

This is a multi-center, prospective cohort study with a comparison to historical control to collect 2-year safety and effectiveness data on 120 subjects, at approximately 6 sites in the United States, who have undergone Navio System-assisted TKA.

Subject data will be evaluated at the pre-operative, operative, one month, six months, one year, and two year follow up visits.

A final analysis will be conducted once all subjects have completed a two year visit.

5. Study Device

The Smith & Nephew Navio Robotic-assisted Surgical System aids the surgeon in planning and executing a procedure involving bone preparation for prosthesis implantation. The system is comprised of computer-assisted surgical instrument control, a commercially available surgical drill, image-free navigation, and planning software with standard navigation technology.

The Navio System uses data gathered during the beginning of the surgical procedure (planning phase) to generate a computer model of the knee surface to be remodeled in preparation for the implant. The software uses data collected during the planning phase along with pre-loaded data describing the implant geometry to guide the surgeon in shaping the knee for the selected implant. The Navio system software then allows the surgeon to evaluate the range of motion and fit of the implant prior to finalizing the procedure.

The Navio system software consists of a patient and user management module, a surgical planner, and an intraoperative cutting module. The surgeon uses patient data collected at the surgical site to align the implant and shape the target surface of the bone to accept the intended implant. The Navio system also uses the tracked position of the surgical bur to control its cutting engagement to the bone that is to receive the implant. This cutting control is based on the bur's proximity to the planned target surface of the bone.

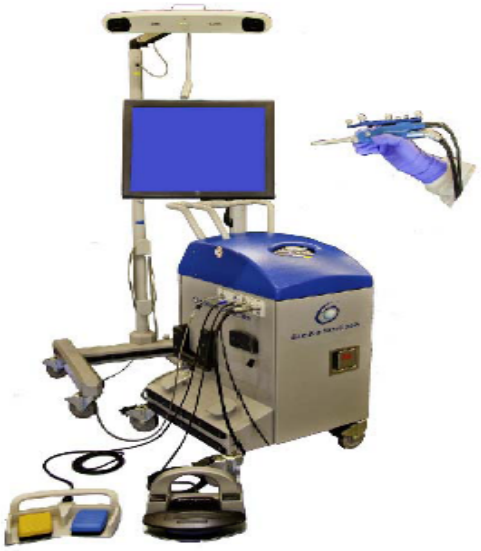
The cutting control is achieved in two ways:

- Exposure control adjusts the bur's exposure with respect to a guard. If the surgeon encroaches on a portion of bone that is not to be cut, the Navio system retracts the spinning bur behind the guard, disabling cutting. The Navio system software also adjusts the depth of the cut by adjusting the exposure of the bur outside of the bur guard.
- Speed control regulates the signal transmitted to the drill motor. This limits the speed of the spinning bur or disables bur motion entirely if the target surface has been reached. Bur motion is also disabled if the bur is moved outside of expected cutting boundaries.

The surgeon can alternate between these two cutting control modes. The surgeon can also disable both cutting control modes and operate the Navio system as a standard navigated drill.

The Navio system incorporates a detailed user interface that provides procedure setup, tracking status, visual indicators, and real-time cutting progress during the procedure.

The Navio System is shown below:



Description	Part Number
Tracking Camera and Stand	110001
Navio System Cart	NPFS-02000, -02010, -02020, -02070
Anspach Drill Foot Control	120041
Navio System Foot Control	100460
Navio System Handpiece	110137
Anspach Drill	101209

The function of each component is as follows:

- Tracking Camera and Stand - The mobile infrared tracking camera is used to determine the position of the point probe and the surgical bur tip and track their movement by scanning the position of reflective trackers relative to the position of trackers mounted on the patient's femur and tibia.
- Navio System Cart - The mobile cart contains the electronic control system, electrical system integration unit, computer, and uninterruptible power supply (UPS). Navio system carts are

available in 120 VAC and 220-240 VAC versions. The cart provides storage for the power cord, Anspach® drill foot control, and the Navio system foot control. The touchscreen monitor is the primary user interface for the Navio system.

- Anspach® Drill Foot Control - The Anspach drill foot control is used to control the Anspach drill during surgery. The surgeon must press the foot control to activate the bur. The speed of the bur is controlled by the Navio system software in speed control mode.
- Navio System Foot Control - The Navio system foot control is used as an alternative to the touchscreen monitor when data points are being collected to define landmarks, shape bone, and position the implant prior to surgery.
- Navio System Handpiece - The Navio system handpiece controls the position of the Anspach Drill and bur relative to the position of the guard and the desired profile of the bone being cut. In exposure mode, as the bur nears the target surface of the bone intended to accept the implant, the Anspach drill and bur retracts into the guard to prevent further cutting of bone.

The Navio system is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures. The system is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. These procedures include UKR and patellofemoral arthroplasty. The Navio System is indicated for use with cemented implants only (refer to User Manuals for more detail).

5.1. Surgical Technique

The Navio System is to be used per standard of care at the participating study sites. Each participating investigator will have performed a minimum of 8 Navio TKA procedures prior to enrolling subjects on this study. The Navio System is indicated for Smith & Nephew cemented Total Knee implants, but for the purposed of this study we are restricting the type of implant to the Journey II BCS or Cruciate-Retraining (CR) Systems and compatible S&N patellar implants. The list of acceptable part numbers can be found in Appendix 1. The patella must be resurfaced during the primary TKA procedure.

6. STUDY POPULATION

6.1. Subject Screening & Enrollment

To eliminate the potential for selection bias, Investigators should screen all subjects undergoing a Navio® assisted TKA. In order to do so, only the existing information obtained per standard routine medical procedures will be used. No study-specific screening procedures, activities or questionnaires will be performed during pre-screening.

Once a subject has completed the informed consent procedure and signed the Informed Consent Form, the Principle Investigator (PI), or delegated study research staff, can complete the screening process with the subject. All potential subjects who undergo the screening process will be documented on a Screening and Enrollment Log, on which reasons for exclusion from or denial to participate should be noted. In the event that a subject has a bilateral Navio assisted TKA, only the first knee treated after informed consent will be enrolled in the study.

6.2. Subject Inclusion Criteria

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

1. Subject requires primary total knee arthroplasty with the Journey II BCS or Cruciate-Retraining (CR) Systems due to degenerative joint disease (primary diagnosis of osteoarthritis, post-traumatic arthritis, avascular necrosis, rheumatoid arthritis.
2. Subject was considered skeletally mature at the time of cone implantation (at least 18 years or older.)
3. Subject agrees to consent to and to follow the study visit schedule (as defined in the study protocol and informed consent form) by signing the IRB/EC approved informed consent form.
4. Subject plans to be available through two (2) years postoperative follow-up.

6.3. Subject Exclusion Criteria

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

1. Subject has BMI ≥ 40.
2. Subject has condition(s) that may interfere with the TKA survival or outcome (i.e., Paget's or Charcot's disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease, or an active, local infection).
3. Subject is deemed by investigator to require a constrained or deep dish tibial insert.
4. Subject has inadequate bone stock to support the device (severe osteopenia, history of severe osteoporosis or severe osteopenia).
5. Subject has mental or neurologic condition(s) that may pre-empt the ability or willingness to restrict activities.
6. Subject is 80 years of age or older.
7. Subject is a prisoner or impending incarceration.

7. STUDY PROCEDURES

7.1. Study Schematic

The intervals and schedule of events are provided in Table 1.

Schedule of events (*as needed)	Preop	Op/DC	1 Month	6 Months	1 Year	2 Years
Visit Window	-28 days	0	30±7 days	182±30 days	365±60 days	730±60 days
Informed Consent	√					
Inclusion/Exclusion	√					
Demographics/Medical History	√					
Operative Data Collection		√				
Discharge Data Collection		√				
Mechanical Alignment on Long Leg X-rays	√		√			
Standard AP, Lateral, and Patellar (Skyline or Merchant) X-rays				√	√	√
2011 Knee Society Score	√		√	√	√	√
Quality of Life (EQ-5D-5L)	√		√	√	√	√
Forgotten Joint Score (FJS)	√		√	√	√	√
Adverse Event Assessment		√	√	√	√	√
End of Study/Exit		*	*	*	*	*

* if applicable

7.2. Pre-Operative Visit

Procedures to be completed at the pre-operative visit:

- Confirm informed consent
- Assign a subject study number
- Inclusion/Exclusion
- Demographics and medical history
- 2011 Knee Society Score
- Quality of Life (EQ-5D)
- Forgotten Joint Score
- Perform long leg X-rays to assess Mechanical Alignment

7.3. Surgery

Procedures to be completed at the time of surgery:

- Update information in the Screening and Enrollment Log
- Operative Data including target mechanical alignment
- Discharge Data
- Adverse Event Assessment

7.4. One Month Post-Operative Visit

- Perform long leg X-rays to assess Mechanical Alignment
- 2011 Knee Society Score
- Quality of Life (EQ-5D)
- Forgotten Joint Score
- Obtain and record any AEs occurring from the time of study device implantation
- Adverse Event Assessment

7.5. Six Months, One Year, Two Years Post-Operative

- Perform standard AP, lateral, and patellar X-rays
- 2011 Knee Society Score
- Quality of Life (EQ-5D)
- Forgotten Joint Score
- Obtain and record any AEs occurring from the time of study device implantation
- Adverse Event Assessment
- Collect End of Study Information if applicable

8. Subject Completion and Disposition

8.1. Screening

Subjects considered potential candidates for the study based on pre-screening will sign an IRB/EC approved Informed Consent Form (ICF) prior to any study activities. The PI, or delegated study research staff, may then complete the first study visit with the subject.

8.2. Enrolled Subject

Subject enrollment occurs at the time of surgery. Every subject that has signed consent, is assigned a Subject ID, and received a total knee implant from the Journey II family with surgical assist from the study device will be considered enrolled in the study.

8.3. Conditions for Study Termination

All reasonable efforts should be made to retain the subjects for the 2 year duration of this study. If the subject has a revision of any component, the subject will be terminated from the study.

A. Screening Failure

If a subject has provided consent, completed screening and for any reason is not operated on by the study device and does not receive a total knee implant from the Journey II BCS or Cruciate-Retraining (CR) Systems, the subject will not be considered enrolled in the study.
For these subjects an Inclusion/Exclusion and Informed Consent CRF, Demographics CRF, Medical History CRF, and End of Study CRF need to be completed. However, the CRFs should not be submitted into the Sponsor's database unless the subject signed consent and was assigned a Subject ID.

B. 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 CRF will be completed for all subjects who do not finish the study, and reason for withdrawal will be documented in the form.

C. Lost to Follow-Up

Some actively enrolled subjects may not return for follow-up exams due to a variety of reasons. Study personnel must make reasonable efforts to contact the subject and document the following contact attempts prior to declaring a subject to be lost to follow-up: the subject has been contacted according to the site's policies, but no less than 2 documented phone contacts and 1 certified letter without response. 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 subjects CRF at the site. A subject will be considered lost to follow-up if he/she does not appear for the scheduled study visit for 2 consecutive visits and study personnel are unable to contact the subject.

D. 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 schematic
- subject lost to follow-up

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

- in case any component of the original Journey II hardware is revised/exchanged
- if the Investigator or the Sponsor stops the study for any reason

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

E. 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 obtained; however, the subject will continue to be followed for study visits and information will be collected regarding the outcome of the birth.

F. Study Site Discontinuation

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

- non-compliance to Good Clinical Practice (GCP) or protocol
- failure to enroll subjects
- major protocol deviations
- inaccurate or incomplete data
- unsafe or unethical practices
- safety or performance considerations
- investigator involuntarily discontinues participation in study

9. SAFETY REPORTING

Adverse events and device deficiencies, noted by study staff and reported by the subject, and occurring from the time of study device implantation through study completion should be recorded on the appropriate CRFs and reported as below.

9.1. Definitions for safety reporting

A. Adverse Event (AE)

An AE is 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 [1].

This definition includes:

- events related to the investigational medical device or the comparator
- events related to the procedures involved

B. Serious Adverse Event (SAE)

A SAE is an adverse event that [1]:

- 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) in-patient 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 a serious adverse event.

C. Adverse Device Effect (ADE)

An ADE is an adverse event related to the use of an investigational medical device [1].

This definition includes:

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

D. Serious Adverse Device Effect (SADE)

An SADE is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event [1].

E. Unanticipated Serious Adverse Device Effect (USADE)

A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report or the clinical investigation plan [1,2].

F. Device Deficiency

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

For the purpose of this study, device deficiencies should be reported when they concern any component of the study device or any components of the Journey II implants, as well as its packaging and tools that need to be used during implantation according to the Instructions for Use.

G. Revisions

A specially designed Revision Case Report Form will be used in addition to the Adverse Event Form, to document in detail revisions of any of the components of the study device.

9.2. Safety: Investigator's Responsibilities

Investigators shall record adverse events and observed device deficiencies, together with an assessment of seriousness, severity, and relatedness, in the subject's source data. Following, Investigators are responsible for documenting AEs and device deficiencies on the appropriate CRF and submitting them to the Sponsor according to the timelines described here below.

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

Unresolved AEs should be followed by the Investigator until the events are resolved, the subject is lost to follow-up or through to the end of the study, whichever timing occurs first. Unresolved AEs 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 AEs 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 wellbeing.
- 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 wellbeing and may require medical intervention and/or close follow-up.
- Severe: the adverse event 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 wellbeing. 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 Navio (the study device), the implant and the 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, SAEs*, SADEs, U(S)ADEs and device deficiencies 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.

The Principal Investigator will be responsible for reporting to the IRB/EC of the study site and to the regulatory authorities, SAEs, SADEs and device deficiencies that could have led to a SADE, as required by the national regulations.

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 SAEs that were reported by all sites throughout the clinical investigation and based on perceived risk.
The Sponsor will also, in case of SADEs and device deficiencies that could have led to SADEs, determine whether the risk analysis needs to be updated and assess whether corrective or preventive action is required.

10. Statistical Procedures

10.1. Sample size calculation

Parratte et al.[7] looked at the effects of postoperative mechanical axis alignment on the survival of TKAs. They found that of the 398 TKAs reviewed in the paper there were 292 (73.4%) which post-operatively were defined as mechanically aligned (with a mechanical axis of $0^{\circ} \pm 3^{\circ}$).

This study aims to show superiority in the proportion of TKAs post-operatively defined as mechanically aligned against the reference proportion of 73.4% from above.

It is estimated that the proportion of mechanically aligned TKAs using the Navio system will be around 88%. If this assumption holds then the recruitment of 115 subjects would be sufficient to provide 80% power to show that the lower limit of the two-sided 95% confidence interval for the proportion of mechanically aligned TKAs is greater than 73.4%, hence proving superiority to the reference literature.
It is expected that approximately 5% of subjects will be lost to follow up at the 1 month visit and therefore 120 subjects will be recruited for this study.

10.2. General Statistical Considerations

Smith & Nephew's Global Biostatistics group will conduct the statistical analysis for this study and they will prepare Statistical Analysis Plan (SAP). Unless otherwise stated, all significance tests and hypothesis testing will be two-sided, performed at the 5% significance level. Resulting p-values will be quoted and 95% two-sided confidence intervals will be generated where appropriate. All p-values will be rounded to three decimal places, p-values less than 0.001 will be presented as '<0.001' in all tables.
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 9.4 (or later).

10.3. Missing Data

A complete disposition report, along with the explanation for lost-to-follow-up, death, revision, and withdrawn subjects is to be provided in the Clinical Study Report (CSR). The methods used to handle missing or incomplete data for the efficacy and safety measures will be detailed in the Statistical Analysis Plan (SAP).

10.4. Analysis Populations

All subjects that are operated on by the study device are considered study participants. The following study populations and analysis sets will be defined:

- **Safety Population**: This population will include all subjects that received the study device and will be used for analysis of demographics, disposition data and safety.
- **Modified Intention to Treat Population (mITT)**: Following the intention to treat principle, this population Full Analysis Set (FAS): This will include all subjects that received the study device and attended at least one post-baseline assessment. This population will be used for the primary analysis of all efficacy endpoints.
- **Per Protocol Population (PP)**: This population will include all subjects that received the study device, meet the inclusion/exclusion criteria, attend all follow-up assessments within the specified window, and have no significant protocol deviations. Subjects that are required to be withdrawn from the study under the protocol (e.g. due to revision) will be included regardless of attendance of follow-up visits unless they are deemed to have significant protocol deviations or failed to meet the inclusion/exclusion criteria. This population will be used as secondary analysis of all efficacy endpoints.

10.5. Analysis of Primary Endpoint

The primary endpoint of the study is the proportion of subjects achieving post-operative mechanical alignment, defined as ±3° from target, assessed at the 1 month study visit, and after undergoing a Navio assisted TKA.

The proportion defined above will be presented along with the associated two-sided 95% confidence interval, to be calculated using exact binomial methods.

Superiority of the proportion of subjects achieving post-operative mechanical alignment, after undergoing a Navio assisted TKA against those in the reference literature (Parratte et al.)[7] will be achieved if the lower limit of the two-sided 95% confidence interval is greater than 73.4%.

Mechanical alignment will also be summarized using summary statistics.

10.6. Analysis of Secondary Endpoints:

Implant survival rate will be assessed for a final analysis using the number and proportion of subjects who had no implant revisions by the 2-year time point, the associated 95% confidence intervals will be calculated using exact binomial methods. Time to occurrence of revisions will also be analyzed using Kaplan-Meier survival analysis.

KSS, EQ-5D-5L, and FJS scores will be analyzed separately at the end of study using Repeated Measures ANOVA models, prognostic and baseline factors will be adjusted for.

Length of hospital stay, operative time (both skin to skin time and anesthetic time), and radiographic assessments will be assessed using summary statistics. Trends in operative time measures for individual investigators over the course of the study will be assessed.

10.7. Analysis of Safety Endpoints:

The safety endpoints for this study are the number of occurrences and the frequency of subjects reporting: adverse events (AE), serious adverse events (SAE), adverse device effects (ADE), serious adverse device effects (SADE), unanticipated serious adverse device effects (USADE) and device deficiencies (DevD).

In addition, for each event, the following will be summarised: seriousness, the relationship to the investigational device (Navio), relationship to implant, relationship to study procedure, outcome and either the duration of the resolved events or the duration of the events at study completion.

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 of the study site by the Investigator.

11.3. Informed Consent

All study subjects must sign an IRB/EC approved ICF according to 2011:ISO14155 guidelines, GCP guidelines and all applicable national regulations. Potential subjects must be informed as to the purpose of the study and the potential risks and benefits known or that can be reasonably predicted or expected as described in the written consent form. The subject shall have sufficient opportunity to consider participation in the study; a subject cannot be led to believe that he/she is waiving his/her rights as a subject or the liability of the Sponsor or Investigator. Subjects are then invited to sign and date the consent form, indicating their consent for enrollment. The Investigator will retain the original copy of the signed consent form in the study files. A duplicate copy shall be provided to the subject.

11.4. Risk – Benefit Analysis

A. Study Related Risks

Possible risks that may occur as a result of study procedures are:

- Subjects will be asked to complete questionnaires; however these are not interventional procedures and are not expected to add significant time to any appointments.
- This study involves the use of x-ray evaluation. X-ray exposure is cumulative over a lifetime and total exposure should be kept to a minimum. However, if the x-ray exposure when participating in the

study is equivalent to the exposure the subject would receive if they chose not to participate in the study, there is no additional risk associated with this study.

- 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.

Risks related to the general surgical procedures are not considered here because these could be present regardless of participation into the study.

B. Study Related Benefits

Because the surgery and all the follow-up visits are the same as if the subject would 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 TKA.

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 follows: 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.
Original CRFs may be used as source documents only in the case of 2011 Knee Society Score, Quality of Life (EQ-5D) and the Forgotten Joint Score.

The Principal Investigator shall ensure that clinical records are clearly marked to indicate that the subject is enrolled in a particular clinical study and if he/she completed per protocol or discontinued early and the reason.

12.2. Direct Access

This study may 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 wellbeing 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 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

A study close out visit will be performed by the Sponsor or designee to retrieve and account for all remaining clinical data and to resolve outstanding queries. 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

The Sponsor, Sponsor's agents, IRB/EC and regulatory agencies may audit study data. The site must accommodate audit requests, notify the Sponsor of any requests as soon as they are received, and provide direct access to study records during the audit.

12.8. Data Handling and Record Keeping Requirements

Case report forms (CRFs) will be supplied by the Sponsor. Subjects will be identified by a study number and subject identification code. Only the Investigator site will have the key to identify individual subjects. The Investigator is responsible for the timely and accurate completion of CRFs. 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 case report forms (CRFs) at the time of the scheduled visits. Once a subject is enrolled, completed CRFs should be sent to the Sponsor, either by fax or by e-mail, as soon as possible, and is generally expected within 10 working days upon completion of the CRFs.

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 accidental or premature destruction of those documents. The investigator must retain essential study documents for at least 2 years after the latest of the following: the date the study is terminated or completed or the date the documents are no longer needed to support a premarket approval application. 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 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 through the specially designed Protocol Deviation Log 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 of the study site. It is the responsibility of the PI to inform the IRB/EC of the study site 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 (CAPA).

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.

BIBLIOGRAPHY

List all relevant references here.

1. ISO 14155:2011
2. 21 CFR 812
3. ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
4. Rand, et al, J Arthroplasty (1991) Sep; 6(3);279-84
5. 2015 Hip and Knee Implant Review, www.OrthopedicNetworkNews.com
6. Dalton, et al, J. Arthroplasty (2016) 31, 1366-1372
7. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of Postoperative Mechanical Axis Alignment on the Fifteen-Year Survival of Modern, Cemented Total Knee replacements. JBJS 2010:92:2143-9

Appendix 1
JOURNEY II BCS and CR Component Part Numbers

JOURNEY II FEMORALS	

Catalog Item Number	Description
7402-2111	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 1
7402-2112	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 2
7402-2113	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 3
7402-2114	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 4
7402-2115	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 5
7402-2116	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 6
7402-2117	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 7
7402-2118	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 8
7402-2119	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 9
7402-2110	JOURNEY II BCS FEMORAL OXINIUM RIGHT SIZE 10
7402-2121	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 1
7402-2122	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 2
7402-2123	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 3
7402-2124	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 4
7402-2125	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 5
7402-2126	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 6
7402-2127	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 7
7402-2128	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 8
7402-2129	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 9
7402-2120	JOURNEY II BCS FEMORAL OXINIUM LEFT SIZE 10
7402-4211	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 1
7402-4212	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 2
7402-4213	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 3
7402-4214	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 4
7402-4215	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 5
7402-4216	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 6
7402-4217	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 7
7402-4218	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 8
7402-4219	JOURNEY II BCS FEMORAL COCR RIGHT SIZE 9
7402-4921	JOURNEY II BCS FEMORAL COCR LEFT SIZE 1
7402-4922	JOURNEY II BCS FEMORAL COCR LEFT SIZE 2
7402-4923	JOURNEY II BCS FEMORAL COCR LEFT SIZE 3
7402-4924	JOURNEY II BCS FEMORAL COCR LEFT SIZE 4
7402-4925	JOURNEY II BCS FEMORAL COCR LEFT SIZE 5
7402-4926	JOURNEY II BCS FEMORAL COCR LEFT SIZE 6
7402-4927	JOURNEY II BCS FEMORAL COCR LEFT SIZE 7

JOURNEY II FEMORALS	
7402-4928	JOURNEY II BCS FEMORAL COCR LEFT SIZE 8
7402-4929	JOURNEY II BCS FEMORAL COCR LEFT SIZE 9
7402-1151	JOURNEY II CR FEMORAL OXINIUM RT SZ1
7402-1152	JOURNEY II CR FEMORAL OXINIUM RT SZ2
7402-1153	JOURNEY II CR FEMORAL OXINIUM RT SZ3
7402-1154	JOURNEY II CR FEMORAL OXINIUM RT SZ4
7402-1155	JOURNEY II CR FEMORAL OXINIUM RT SZ5
7402-1156	JOURNEY II CR FEMORAL OXINIUM RT SZ6
7402-1157	JOURNEY II CR FEMORAL OXINIUM RT SZ7
7402-1158	JOURNEY II CR FEMORAL OXINIUM RT SZ8
7402-1159	JOURNEY II CR FEMORAL OXINIUM RT SZ9
7402-1150	JOURNEY II CR FEMORAL OXINIUM RT SZ10
7402-1161	JOURNEY II CR FEMORAL OXINIUM LT SZ1
7402-1162	JOURNEY II CR FEMORAL OXINIUM LT SZ2
7402-1163	JOURNEY II CR FEMORAL OXINIUM LT SZ3
7402-1164	JOURNEY II CR FEMORAL OXINIUM LT SZ4
7402-1165	JOURNEY II CR FEMORAL OXINIUM LT SZ5
7402-1166	JOURNEY II CR FEMORAL OXINIUM LT SZ6
7402-1167	JOURNEY II CR FEMORAL OXINIUM LT SZ7
7402-1168	JOURNEY II CR FEMORAL OXINIUM LT SZ8
7402-1169	JOURNEY II CR FEMORAL OXINIUM LT SZ9
7402-1170	JOURNEY II CR FEMORAL OXINIUM LT SZ10
7402-1251	JOURNEY II CR FEMORAL COCR RT SZ 1
7402-1252	JOURNEY II CR FEMORAL COCR RT SZ 2
7402-1253	JOURNEY II CR FEMORAL COCR RT SZ 3
7402-1254	JOURNEY II CR FEMORAL COCR RT SZ 4
7402-1255	JOURNEY II CR FEMORAL COCR RT SZ 5
7402-1256	JOURNEY II CR FEMORAL COCR RT SZ 6
7402-1257	JOURNEY II CR FEMORAL COCR RT SZ 7
7402-1258	JOURNEY II CR FEMORAL COCR RT SZ 8
7402-1259	JOURNEY II CR FEMORAL COCR RT SZ 9
7402-1261	JOURNEY II CR FEMORAL COCR LT SZ 1
7402-1262	JOURNEY II CR FEMORAL COCR LT SZ 2
7402-1263	JOURNEY II CR FEMORAL COCR LT SZ 3
7402-1264	JOURNEY II CR FEMORAL COCR LT SZ 4
7402-1265	JOURNEY II CR FEMORAL COCR LT SZ 5
7402-1266	JOURNEY II CR FEMORAL COCR LT SZ 6
7402-1267	JOURNEY II CR FEMORAL COCR LT SZ 7
7402-1268	JOURNEY II CR FEMORAL COCR LT SZ 8
7402-1269	JOURNEY II CR FEMORAL COCR LT SZ 9

JOURNEY II Tibia baseplates	
Catalog Item Number	**Description**
7402-2211	JOURNEY Tibial Baseplate Nonporous Right Size 1
7402-2212	JOURNEY Tibial Baseplate Nonporous Right Size 2
7402-2213	JOURNEY Tibial Baseplate Nonporous Right Size 3
7402-2214	JOURNEY Tibial Baseplate Nonporous Right Size 4
7402-2215	JOURNEY Tibial Baseplate Nonporous Right Size 5
7402-2216	JOURNEY Tibial Baseplate Nonporous Right Size 6
7402-2217	JOURNEY Tibial Baseplate Nonporous Right Size 7
7402-2218	JOURNEY Tibial Baseplate Nonporous Right Size 8
7193-3635	JOURNEY Tibial Baseplate Nonporous Right Size 9
7402-2221	JOURNEY Tibial Baseplate Nonporous Left Size 1
7402-2222	JOURNEY Tibial Baseplate Nonporous Left Size 2
7402-2223	JOURNEY Tibial Baseplate Nonporous Left Size 3
7402-2224	JOURNEY Tibial Baseplate Nonporous Left Size 4
7402-2225	JOURNEY Tibial Baseplate Nonporous Left Size 5
7402-2226	JOURNEY Tibial Baseplate Nonporous Left Size 6
7402-2227	JOURNEY Tibial Baseplate Nonporous Left Size 7
7402-2228	JOURNEY Tibial Baseplate Nonporous Left Size 8
7193-3634	JOURNEY Tibial Baseplate Nonporous Left Size 9

JOURNEY II TKA Inserts	
Catalog Item Number	**Description**
7402-7211	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 9MM
7402-7212	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 10MM
7402-7213	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 11MM
7402-7214	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 12MM
7402-7215	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 13MM
7402-7216	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 15MM
7402-7217	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 18MM
7402-7218	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 RIGHT 21MM
7402-7221	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 9MM
7402-7222	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 10MM
7402-7223	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 11MM
7402-7224	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 12MM
7402-7225	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 13MM
7402-7226	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 15MM
7402-7227	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 18MM
7402-7228	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 1-2 LEFT 21MM

JOURNEY II TKA Inserts	
7402-7231	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 9MM
7402-7232	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 10MM
7402-7233	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 11MM
7402-7234	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 12MM
7402-7235	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 13MM
7402-7236	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 15MM
7402-7237	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 18MM
7402-7238	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 RIGHT 21MM
7402-7241	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 9MM
7402-7242	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 10MM
7402-7243	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 11MM
7402-7244	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 12MM
7402-7245	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 13MM
7402-7246	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 15MM
7402-7247	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 18MM
7402-7248	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 3-4 LEFT 21MM
7402-7251	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 9MM
7402-7252	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 10MM
7402-7253	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 11MM
7402-7254	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 12MM
7402-7255	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 13MM
7402-7256	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 15MM
7402-7257	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 18MM
7402-7258	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 RIGHT 21MM
7402-7261	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 9MM
7402-7262	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 10MM
7402-7263	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 11MM
7402-7264	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 12MM
7402-7265	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 13MM
7402-7266	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 15MM
7402-7267	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 18MM
7402-7268	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 5-6 LEFT 21MM
7402-7271	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 9MM
7402-7272	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 10MM
7402-7273	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 11MM
7402-7274	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 12MM
7402-7275	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 13MM
7402-7276	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 15MM
7402-7277	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 18MM
7402-7278	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 RIGHT 21MM
7402-7281	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 9MM
7402-7282	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 10MM
7402-7283	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 11MM

JOURNEY II TKA Inserts	
7402-7284	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 12MM
7402-7285	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 13MM
7402-7286	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 15MM
7402-7287	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 18MM
7402-7288	JOURNEY II BCS XLPE ARTICULAR INSERT SZ 7-8 LEFT 21MM
7402-5611	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 9MM
7402-5612	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 10MM
7402-5613	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 11MM
7402-5614	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 12MM
7402-5615	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 13MM
7402-5616	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 15MM
7402-5617	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 RIGHT 18MM
7402-5621	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 9MM
7402-5622	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 10MM
7402-5623	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 11MM
7402-5624	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 12MM
7402-5625	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 13MM
7402-5626	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 15MM
7402-5627	JOURNEY II CR XLPE ARTICULAR INSERT SZ 1-2 LEFT 18MM
7402-5631	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 9MM
7402-5632	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 10MM
7402-5633	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 11MM
7402-5634	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 12MM
7402-5635	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 13MM
7402-5636	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 15MM
7402-5637	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 RIGHT 18MM
7402-5641	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 9MM
7402-5642	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 10MM
7402-5643	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 11MM
7402-5644	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 12MM
7402-5645	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 13MM
7402-5646	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 15MM
7402-5647	JOURNEY II CR XLPE ARTICULAR INSERT SZ 3-4 LEFT 18MM
7402-5651	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 9MM
7402-5652	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 10MM
7402-5653	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 11MM
7402-5654	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 12MM
7402-5655	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 13MM
7402-5656	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 15MM

JOURNEY II TKA Inserts	
7402-5657	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 RIGHT 18MM
7402-5661	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 9MM
7402-5662	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 10MM
7402-5663	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 11MM
7402-5664	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 12MM
7402-5665	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 13MM
7402-5666	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 15MM
7402-5667	JOURNEY II CR XLPE ARTICULAR INSERT SZ 5-6 LEFT 18MM
7402-5671	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 9MM
7402-5672	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 10MM
7402-5673	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 11MM
7402-5674	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 12MM
7402-5675	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 13MM
7402-5676	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 15MM
7402-5677	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 RIGHT 18MM
7402-5681	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 9MM
7402-5682	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 10MM
7402-5683	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 11MM
7402-5684	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 12MM
7402-5685	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 13MM
7402-5686	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 15MM
7402-5687	JOURNEY II CR XLPE ARTICULAR INSERT SZ 7-8 LEFT 18MM

Patellar Implants		
J 2 Patella Resurfacing		
	Catalog #	**Size (mm)**
	74024826	26
	74024829	29
	74024832	32
	74024835	35
	74024838	38
	74024841	41
J 2 Patella, Biconvex		
	74024623	23
	74024626	26
	74024629	29
	74024632	32
Genesis 2 Patella, Biconvex		
	71420566	23
	71420568	26
	71420570	29

Patellar Implants		
	71420572	32
Genesis 2 Patella, Resurfacing		
	71420580	26
	71420574	29
	71420576	32
	71420578	35
Genesis 2 Patella, Oval Resurfacing		
	71421029	29
	71421032	32
	71421035	35
	71421038	38
	71421041	41