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DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

DePuy Synthes CLINICAL RESEARCH	
CLINICAL INVESTIGATION PLAN (CIP)	
Prospective, Randomized, Multi-center Post-Market study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.	
Clinical Investigation Plan (CIP) Number:	DSJ_2019_03
Country:	United States of America
CIP Prepared By:	PPD PPD E-mail: PPD
CIP Version:	Date: 04OCT2021 Version: 2.0
Sponsor:	Medical Device Business Services, Inc. (hereafter referred to as DePuy Synthes)
Sponsor Address:	700 Orthopaedic Drive P.O. Box 988 Warsaw, IN 46581 Fax: (574) 371-4950

PPD

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Adobe Acrobat Reader version: 2020.013.20064

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PROTOCOL SIGNATURE PAGE

DSJ_2019_03: Prospective, Randomized, Multi-center study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.				
Type	**Version**	**Version Date**	**Description of Changes**	**Effective Date**
Original	1.0	26JUN2019	NA, original protocol	27JUN2019
Amendment	2.0	04OCT2021	▪ Removal of exploratory endpoint ▪ Increased number of sites ▪ Clarification of narcotic pain medication data collection as patient reported ▪ Clarification in section 7.3 – End of Study CRF if needed instead of required ▪ Clarification of analysis datasets/planned treatment (sections 1, 3.4, 10.2)	16DEC2021

I have read this protocol and agree to conduct this clinical investigation plan in accordance with the design and specific provisions outlined herein.

I understand I am solely responsible to ensure the investigation is conducted in accordance with applicable regulations, local regulations, and the signed agreement with DePuy Synthes and with the protocol outlined herein.

I will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting all study commitments.

I will fulfill the requirements of my Institutional Review Board (IRB) to ensure complete and continual oversight of this clinical investigation.

I will use an Informed Patient Consent Form approved by DePuy Synthes and my reviewing oversight committee.

I agree to report all information or data in accordance with the protocol and, in particular, I agree to report any adverse events as defined in this protocol to DePuy Synthes and my reviewing oversight committee as applicable.

I agree to permit DePuy Synthes, FDA, the IRB or other regulatory authorities' direct access to all records, including source data/documents, relating to the clinical investigation, whether paper-based or electronic data capture (EDC).

The below signature confirms I have read and understood this clinical investigational plan and its associated amendments or exhibits and will accept respective revisions or amendments provided by DePuy Synthes.

PRINTED OR TYPED NAME	**SIGNATURE**	**DATE**
Clinical (Principal) Investigator		
Site/Institution Name	**Site Address**	

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Protocol Synopsis	
Title:	**Prospective, Randomized, Multi-center study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.**
Short Title:	Anterior Advantage with KINCISE™
Sponsor:	Medical Device Business Services, Inc.
Indication:	Primary Total Hip Arthroplasty (THA)
Study Article Description:	The KINCISE™ Surgical Automated System (KINCISE) is intended for use in delivering power to DePuy Synthes surgical instruments to impact hard tissue or bone during surgical procedures, and in the placement and removal of implants and instrumentations; including acetabular cups, femoral implants, and broaches.
Study Design:	This is a post-market prospective, 1:1 randomized, multicenter non-inferiority study to compare the femoral broaching time for THA with the Anterior Advantage approach with KINCISE vs. without KINCISE. Follow-up will continue through 24 weeks post-op.
Number of Sites:	Up to twenty (20) study sites will participate
Study Population:	Subjects indicated to receive primary uncemented THA with the Anterior Advantage approach at participating sites who meet the inclusion/exclusion criteria for this study and provide written informed consent to participate.

Protocol Synopsis	
Title:	**Prospective, Randomized, Multi-center study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.**
Sample Size:	N=400 (200 with KINCISE; 200 without KINCISE)
Study Duration:	The anticipated duration of this investigation is approximately 2 and a half years: ▪ It may take approximately 3 to 6 months for each site to complete contracting and obtain IRB/EC review and approval ▪ It may take up to 12 months from the time of study initiation to enroll Subjects and collect and enter study data ▪ It may take approximately 6 months to collect data for the 24-week postoperative follow up visit ▪ It may take approximately 6 months for data cleaning, site closure and final study reports
Primary Objective and Endpoints:	The primary endpoint is femoral broaching time (in minutes), which is collected intraoperatively. The primary objective is to demonstrate that femoral broaching time with KINCISE is non-inferior to femoral broaching time with manual instruments (not using KINCISE) when used in THA with Anterior Advantage. ▪ **Note:** If non-inferiority is successfully demonstrated, then the study will be deemed to be successful, and a test for superiority of femoral broaching time will be conducted.

Protocol Synopsis	
Title:	**Prospective, Randomized, Multi-center study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.**
Secondary Objectives and Endpoints:	If the primary endpoint analysis successfully demonstrates non-inferiority of femoral broaching time, then the following three secondary objectives will be assessed with formal hypotheses, in order, under a gatekeeping strategy: ▪ Non-inferiority of skin-to-skin OR time when KINCISE is used vs. when KINCISE is not used. ▪ Non-inferiority of the percent of subjects with optimal acetabular cup abduction angle when KINCISE is used vs. when KINCISE is not used. ▪ Non-inferiority of the percent of subjects with optimal acetabular cup version angle when KINCISE is used vs. when KINCISE is not used. In addition, the following secondary endpoints do not have prospectively planned hypotheses; these will be summarized for both treatment groups: ▪ Harris Hip Score (HHS) and HHS change from preoperative baseline ▪ Forgotten Joint Score (FJS) and FJS change from 6-week postoperative baseline ▪ EQ-5D-5L and changes in these assessments from preoperative baseline ▪ Pain (Groin, Thigh, and Buttock) ▪ Patient Satisfaction ▪ Post-op time when functional activities can be accomplished (return to work; self-care; etc.) ▪ Radiographic Outcomes (based upon: AP Hip, AP Pelvis, and Lateral) ▪ Length of hospital stay after index THA ▪ Re-hospitalizations during the study (including a specific summary of re-hospitalizations within 90 days) ▪ Narcotic drug usage throughout the study (patient reported) ▪ Complications (including a specific summary of complications within 90 days post-surgery)

Protocol Synopsis	
Title:	**Prospective, Randomized, Multi-center study of Anterior Advantage Surgical Approach in Total Hip Arthroplasty with and without the KINCISE™ Surgical Automated System.**
Procedure Schedule:	Subjects will be seen at the following intervals: preoperative, operative, immediate postoperative (discharge), and 6, and 24 weeks postoperatively
Safety:	Device and procedure related adverse events (AEs) and serious adverse events (SAEs) will be collected

Table 0-1 Time and Events Table

eCRF Name	Data Collection	Pre-op	Operative	Immediate Post-op	6 week	24 week
		Day -180 to DOS	Day 0	Day 0 to Discharge	Day 14 to Day 60	Day 61 to Day 200
N/A	Informed Consent	X				
eCRF SV	Study Visit	X	X		X	X
eCRF ELIG	Eligibility	X				
eCRF RDM	Randomization	X				
eCRF DM	Demographics	X				
eCRF MH	Medical History	X				
eCRF VS	Height & Weight	X				
eCRF PP	Preoperative Planning details	X				
eCRF CM	Narcotic Pain Medications	X	X	X	X	X
eCRF HH	Harris Hip	X			X	X
eCRF HE1	Preoperative Hip Evaluation	X				
eCRF HE2	Postoperative Hip Evaluation				X	X
eCRF HE3	Postoperative Hip Evaluation – Functional Outcomes				X	X*
eCRF SG	Operative Details		X			
eCRF DX	Device Log		X			
eCRF SG	Discharge Details			X		
eCRF EQ5D	EQ-5D-5L	X			X	X
eCRF FJS	Forgotten Joint Score (FJS-12)				X	X
N/A	Pre-op templates used for planning (as	X				

eCRF Name	Data Collection	Pre-op	Operative	Immediate Post-op	6 week	24 week
		Day -180 to DOS	Day 0	Day 0 to Discharge	Day 14 to Day 60	Day 61 to Day 200
	applicable – see section 7.1 for details)					
N/A	AP Hip (unilateral)	X (weight-bearing preferred)			X (weight-bearing)	X (weight-bearing)
N/A	Lateral	X (Modified Lauenstein preferred)			X (Modified Lauenstein preferred)	X (Modified Lauenstein preferred)
N/A	AP Pelvis (bilateral)	X (weight-bearing preferred)			X (weight-bearing)	X (weight-bearing)
eCRF PV	Protocol Deviation	As needed	As needed	As needed	As needed	As needed
eCRF AE	Adverse Event		As needed	As needed	As needed	As needed
eCRF DE	Device Deficiency		As needed	As needed	As needed	As needed
eCRF DS	End of Study (Withdrawal) Form	As needed	As needed	As needed	As needed	X (unless completed previously)

** The functional Outcomes portion of the Hip Evaluation CRF (HE3) will be initially completed at the 6 week visit, and only questions that are marked as "still cannot do" or "still have not returned to work" will be addressed at subsequent study visits*

1 Introduction

Anterior approach total hip arthroplasty (THA) has been shown to be successful through improved early post-operative patient outcomes and faster recovery[1-3], reduced pain[1,3,4], reduced narcotic use[3,5,6], decreased rates of dislocation[7,8], reduced length of stay[1-3,5,6], improved cup positioning[6,9-13], and acceptable complication rates[1,6,14-16] when compared with other surgical approaches. The anterior approach allows the surgeon to work between muscles and tissue without needing to release muscles or tendons from the pelvis or femur[17-19].

Anterior Advantage™ is a DePuy Synthes branded anterior approach with use of DePuy products, and more prescriptively, use of an orthopaedic table and intraoperative fluoroscopy (Matta Method™). See Figure 1-1 below for more information about these surgical approaches.

Figure 1-1: Anterior Advantage

Anterior Approach

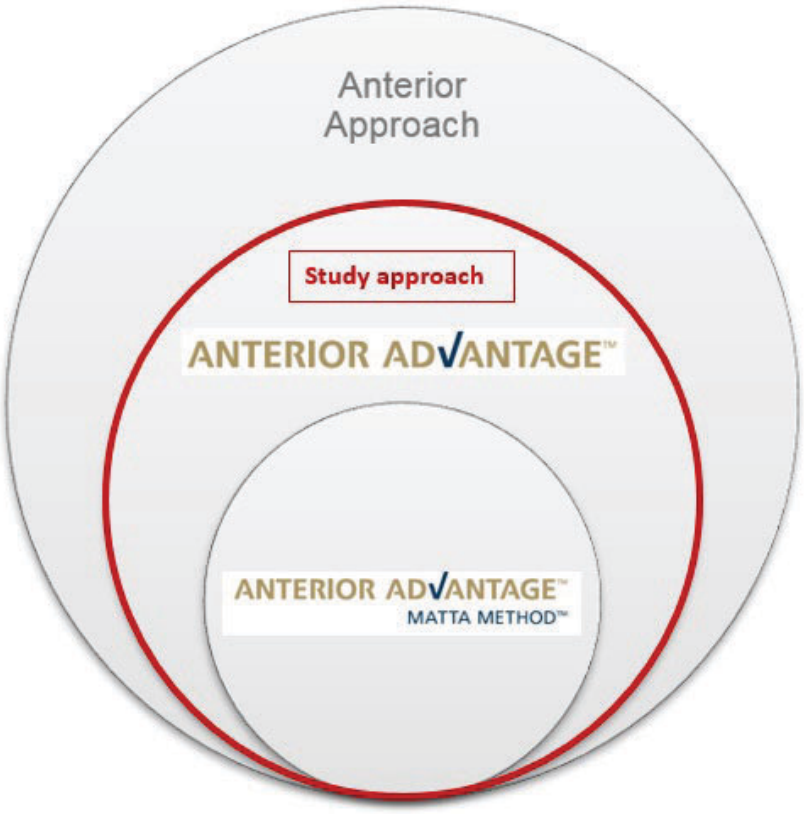
- Any Anterior Approach
- Product agnostic
- OSI, Hana® or Standard OR Table
- With or without intra-operative image check

Anterior Advantage

- Anterior Approach that uses DePuy Synthes products
- OSI, Hana or Standard OR Table
- With or without intra-operative image check

Anterior Advantage Matta Method

- Anterior Approach that uses DePuy Synthes products and;
- OSI, Hana® or other fracture type Table, with;
- Intra-operative image for cup placement



The KINCISE Surgical Automated System™ (KINCISE) (see **Figure 1-2** below) was developed to help automate specific steps of hip replacement surgery. KINCISE can be used by the surgeon to:

- Prepare femur for the final stem using femoral broaches
- Implant stem into femur
- Implant cup in the acetabulum
- Impact head onto femoral stem
- Impact liner into cup

These steps are typically performed with a mallet during THA. By using KINCISE, there is potential to reduce a surgeon's variability, fatigue, and injury during THA. There is also potential to reduce the variability of each impaction step in which KINCISE is used through reproducible and consistent application of force.

Figure 1-2: KINCISE Surgical Automated System™

For this protocol, any Pinnacle cup indicated for primary THA can be included. For the femoral replacement, only Subjects who will receive Corail or Actis stems will be permitted to be enrolled under this protocol. The surgeon should use the same stem for all treated subjects throughout the course of the study (i.e., not a mix of Actis and Corail stems). Please see **Section 12** for more information about the study devices and **Exhibit B** for the specific device product codes allowed. The surgeon should use the assigned treatment throughout the case. For instance, if the subject is randomized to the mallet group, the surgeon must use the mallet for all applicable steps during the case and should attempt the same for assignment of KINCISE (see **Section 3.4** below for more detail).

2 Rationale

The aim of this study is to assess the performance of the Anterior Advantage surgical approach in primary total hip arthroplasty with and without the KINCISE Surgical Automated System. The primary objective is to assess the femoral broach time between a group of subjects operated with Anterior Advantage approach with and without KINCISE.

2.1 Duration of Study

The estimated duration of this clinical study is approximately 2 and a half years. This timeline allows one and a half years for site set up and enrollment, 6 months for data collection, and another 6 months for data cleaning, site closure and final study reports. At the time of the 24 week (6-month) postoperative assessment, an End of Study CRF will be completed for every study Subject who has not been prematurely withdrawn (i.e. End of Study CRF was already completed), and study participation will conclude.

3 Subject Definition

3.1 Subject Population

For the purpose of this study, an enrolled "Subject" is defined as an individual who participates in the study by signing the informed consent form.

3.2 Subject Screening

All patients who the investigator deems to be a candidate for a primary THA using the study devices (Pinnacle cup with a Corail or Actis stem) in a primary uncemented THA, and who generally meet the study requirements are potential candidates. Potential study patients should first be consented and then screened for eligibility and should be listed on the Screening and Enrollment Log to document that the patient selection was unbiased (see **Figure 3-1** below). The date of screening, the results of patient screening (included or not) and the primary reason for not including the patient (*e.g.*, does not satisfy eligibility criteria) will be recorded on this log. The original log is to be retained at the Site and a copy sent to the Sponsor regularly during the enrollment period.

3.3 Subject Eligibility (Inclusion and Exclusion Criteria)

Subjects who have an existing ***non-study*** contralateral total hip replacement ***greater than 3 months*** postoperatively at the time of consent may be entered into this study if they qualify based upon the criteria for inclusion and the approved labeling requirements for the Pinnacle/Corail or Pinnacle/Actis devices. Simultaneous or staged bilateral patients are **not** allowed in this study (see **Exclusion Criteria #9**). Only one hip can be enrolled per subject.

Inclusion Criteria

The decision to have hip replacement with the study devices is part of the patient's standard of care path regardless of the research. Subjects meeting **all** of the following criteria will be considered for participation in the study:

1) The patient is undergoing a standard of care primary cementless hip replacement with the Pinnacle cup and a Corail or Actis stem via the Anterior Advantage approach. All devices are to be used according to the approved indications.
2) Individuals who are able to speak, read, and comprehend the Institutional Review Board approved Informed Consent Document and willing and able to provide informed patient consent for participation in the study and have authorized the transfer of his/her information to DePuy Synthes.
3) Individuals who are willing and able to complete follow-up visits and questionnaires as specified by the study protocol.
4) Individuals who are not bedridden per the discretion of the investigator (The intent of "not bedridden" means a permanent situation, not a temporary situation as in a hip fracture or trauma case).
5) Individuals who are a minimum age of 21 years at the time of consent.

Exclusion Criteria

Subjects will be excluded if, in the opinion of the Investigator, the individual meets any of the following exclusions:

1) Active local or systemic infection.
2) Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
3) Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
4) Charcot's or Paget's disease.
5) The Subject is a woman who is pregnant or lactating.
6) Subject had a contralateral amputation.
7) Previous partial hip replacement in affected hip.
8) Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three months.
9) Contralateral hip was replaced less than 3 months prior to surgery date, contralateral hip is already enrolled in the study, or simultaneous or staged hip replacement is planned

10) Subject is currently involved in any personal injury litigation, medical-legal or worker's compensation claims.

11) Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.

12) Subject has a medical condition with less than 2 years of life expectancy.

13) Subject, in the opinion of the Investigator, is a drug or alcohol abuser or has a physical or psychological disorder that could affect their ability to complete patient reported questionnaires or be compliant with follow-up requirements.

3.4 Enrollment, Randomization & Subject Identification (ID) Number

A patient will be enrolled in the study after signing the Institutional Review Board (IRB) approved informed consent form.

Each enrolled patient will be assigned a unique Subject identification number *by the database*. The first two digits of the Subject number represent the site identification number, followed by a hyphen, and three digits representing the sequential identification (*e.g.,* Subject 10-001 is the first number assigned at site 10). The Subject's unique identifier assigned in EDC will be recorded on each page of the eCRF and other study-specific documentation relating to that Subject (e.g. CRF source documents, patient reported outcomes, etc.). Subject numbers will be assigned for all patients who consent to participate in the study.

After the subject is consented, it must be verified that the subject meets all eligibility criteria. Once confirmed, the subject will be randomized into a treatment group. The sponsor will provide stickers in numerical order for each site. The stickers should be removed in numerical order to reveal the randomization code and treatment group for each consecutive consented subject that meets eligibility criteria. The sticker should be placed on the screening log to document that randomization was unbiased. The planned randomization group should then be documented in the applicable source document and on the Randomization eCRF (eCRF RDM) in the database. The subject will be randomized to either the Control – Anterior Advantage ***without*** KINCISE or the STUDY – Anterior Advantage ***with*** KINCISE group.

The flowchart presented below in Figure 3-1 depicts the process flow for screening, enrollment and randomization for the study.

The Principal Investigator must document the Subject's participation in this study in the Subject's clinic and hospital notes. If the subject is randomized to KINCISE, the surgeon should use KINCISE for the femoral broaching and as much as possible throughout the study where a mallet would have typically been used. However, if the surgeon feels it is necessary to use a mallet (i.e. impaction of the cup). Each use of the mallet should be documented on the Operative Details eCRF and in the source documents. If the surgeon uses the mallet as described above, it would not be considered a protocol deviation as long as KINCISE was used for the femoral broaching and as much as possible (per the randomization

assignment and as documented in the source and eCRF). However, KINCISE must be used for the femoral broaching per the randomization assignment; if not, then this would be a protocol deviation. For those subjects randomized to the control group (mallet), the mallet must be used for all steps throughout the surgery.

3.5 Process for Discontinuation of Subject Participation

Subjects who have provided Informed Consent for their participation may discontinue through screen failure, withdrawal or death. In all instances of Subject discontinuation **after obtaining Informed Consent**, an End of Study/Withdrawal CRF is required to be submitted to the Sponsor to document the study Subject's study discontinuation or withdrawal.

3.5.1 Preoperative Screen Failures/Withdrawals

A subject may withdraw consent at any time during the study, even before surgery. The Investigator may withdraw the Subject preoperatively for safety reasons or due to eligibility. For example, a patient may become pregnant during the window between giving consent and the planned surgery.

In all instances when a Subject is withdrawn, the Subject Screening and Enrollment Log must be updated to reflect that Subject's removal/withdrawal from the study. **For this study, in the case a consented subject is determined to be ineligible for participation or withdraws consent before being randomized to a treatment group, this will be defined as a screen failure**. A screen failure which occurs after obtaining consent will also require an End of Study/Withdrawal CRF submitted to the Sponsor. Please refer to **Table 3-1** below for further guidance.

Table 3-1: Preoperative Screen Failure/Withdrawal Examples

Screen Failures		
Example	**Actions**	**Follow-up**
Before consent and before surgery, the patient is determined to be ineligible to participate in the study	Update Screening/Enrollment Log as "Screen Failure" and document reason	Do not continue
After consent and before randomization, Subject is determined to be ineligible	Update Screening/Enrollment Log as "Screen Failure" and document reason **and** Submit preoperative CRFs and End of Study/Withdrawal CRF to the Sponsor	Do not continue
Subject Withdrawal		
Example	**Actions**	**Follow-up**
After consent and randomization, and before surgery, Subject is determined to be ineligible	Submit preoperative CRFs and End of Study/Withdrawal CRF to the Sponsor	Do not continue
After consent and randomization, but before surgery, Subject withdraws consent	Submit preoperative CRFs and End of Study/Withdrawal CRF to the Sponsor	Do not continue

3.5.2 Intraoperative Withdrawals

The investigator may withdraw the Subject intraoperatively for safety reasons. For example, it may become clear that the patient is not suited to receive the devices outlined in this protocol. If the subject is withdrawn intraoperatively, the preoperative data and an End of Study eCRF should be submitted, along with an adverse event eCRF if applicable. Please refer to **Table 3-2** below for further guidance.

Table 3-2: Intraoperative Withdrawal Examples

Intraoperative Withdrawal – Potential Subjects determined to be ineligible for study participation intraoperatively		
Example	**Actions**	**Follow-up**
Intraoperatively determined to be ineligible because the patient's bone quality is not sufficient to meet eligibility criterium	Submit preoperative CRFs and End of Study/Withdrawal CRF indicating 'Intraoperative Withdrawal' (with specified reason for decision noted) to the Sponsor **and** inform the Subject that they were withdrawn	Do not continue

3.5.3 Enrollment Replacement Rules

Since Subjects are enrolled at the time of consent, any Subject that is withdrawn preoperatively or intraoperatively **will be replaced with subsequent Subjects**. Overall, the number of subjects that receive the study devices per the techniques specified by this protocol across all sites must meet the sample size of 400 (200 per treatment group).

3.5.4 Postoperative Withdrawal

A postoperative withdrawal is a Subject who has signed the Informed Consent Form and has been randomized, has received the standard of care study devices, and is later withdrawn from study participation (i.e. withdrawal of consent, revision, death, etc.). See **Table 3-3** below for more examples. All data obtained up to the date of withdrawal will be included in the clinical analysis.

Table 3-3: Postoperative Withdrawal Examples

Example	Actions	Follow-up
Subject withdraws consent	Document Subject's request for withdrawal from the study **and** Complete End of Study/Withdrawal CRF	Do not continue
Death	Complete Adverse Event CRF **and** Complete End of Study/Withdrawal CRF	Do not continue
Revision	See **Section 3.5.5** below for more information	Do not continue if the metal cup or stem has been revised.

3.5.5 Revisions/Reoperations

A revision is defined as a surgical procedure of the affected hip where one or more of the THA components (acetabular cup, femoral stem, femoral head, or liner) are removed. In the event that a Subject must undergo revision of either the stem or the cup before completing the study, the Subject will be withdrawn from study participation and an Adverse Event (AE)/Serious Adverse Event (SAE) CRF and an End of Study/Withdrawal CRF should be completed. ***In the event that the head or the liner is exchanged, but the cup and stem are not revised, the subject should remain in the study and continue to be followed.***

A reoperation is defined as any surgical procedure of the affected hip in which no THA components are removed. These subjects are not to be withdrawn. An Adverse Event (AE) CRF must be completed in this case. See **Table 3-4** below for more information on revisions and reoperations.

Table 3-4: Revision and Reoperation Examples

Revision – A surgical procedure of the affected hip where one or more of the THA components (acetabular cup, femoral stem, femoral head, or liner) are removed. If the acetabular cup or femoral stem is revised, the Subject is to be withdrawn from study participation		
Example	**Actions**	**Follow-up**
Removal or revision of the acetabular cup implant	Complete Adverse Events (AE) CRF and End of Study/Withdrawal CRF	Do not continue
Revision of the femoral stem implant	Complete Adverse Events (AE) CRF and End of Study/Withdrawal CRF	Do not continue
Exchange of the liner	Complete Adverse Events (AE) CRF	Continue follow up
Reoperation – Any surgical procedure of the affected hip in which no THA components are removed		
Example	**Actions**	**Follow-up**
Irrigation and debridement with no components removed	Complete Adverse Events (AE) CRF	Continue follow up
Surgical reduction of hip after dislocation	Complete Adverse Events (AE) CRF	Continue follow up

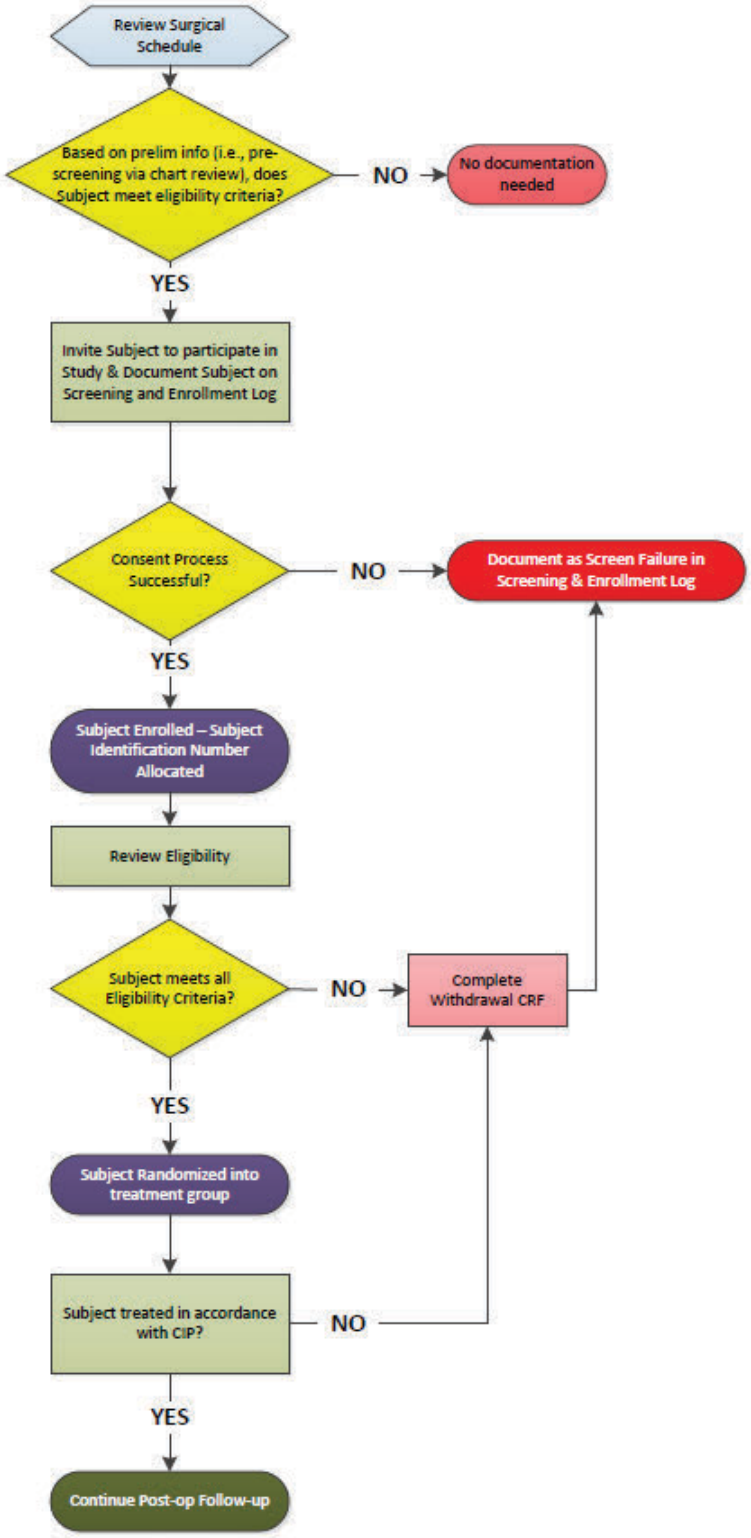
3.5.6 Minimization of Subjects Lost to Follow-up

Although follow up compliance is essential to study quality, some Subjects may not be able or willing to return for their scheduled follow-up evaluations as prescribed in the protocol. Given the short duration of the follow-up for this study, this is not expected to occur often.

Sites should make every effort to ensure complete follow-up whenever possible through phone calls and written requests to a Subject. Each Investigator must maintain a record of communications and/or attempts at communication in the source documentation.

A subject can be classified as "lost-to-follow-up" and subsequently withdrawn from the study only after the site has documented in the medical record at least two unsuccessful attempts of contact.

Figure 3-1: Screening, Enrollment and Randomization Process



4 Objectives, Endpoints, and Associated Hypotheses

4.1 Primary Objective, Endpoint, and Associated Hypotheses

The primary endpoint is the mean femoral broaching in minutes collected intraoperatively. ***Femoral broach time should be collected intraoperatively in minutes and seconds and should begin at the time the box osteotome first enters the femoral canal and end with seating of the final broach trial within the femoral canal.***

The primary objective of this study is to demonstrate that the mean femoral broaching time with KINCISE is non-inferior to the mean femoral broaching time with manual instruments when used in THA with Anterior Advantage.

If non-inferiority is successfully demonstrated then the study will be deemed successful, and a test for superiority for mean femoral broaching time will be conducted.

4.2 Secondary Objectives, Endpoints, and Associated Hypotheses

If the primary endpoint analysis successfully demonstrates non-inferiority of mean femoral broaching time, then the following secondary endpoints will be assessed with formal hypotheses, in order, under a gatekeeping strategy

- Non-inferiority of skin-to-skin OR time when KINCISE is used vs. when KINCISE is not used.
- Non-inferiority of the percent of subjects with optimal acetabular cup abduction angle when KINCISE is used vs. when KINCISE is not used.
- Non-inferiority of the percent of subjects with optimal acetabular cup version angle when KINCISE is used vs. when KINCISE is not used.

In addition, the following secondary endpoints do not have prospectively planned hypotheses; these will be summarized for both treatment groups:

- Harris Hip Score (HHS) and HHS change from preoperative baseline
- Forgotten Joint Score (FJS) and FJS change from 6-week postoperative baseline
- EQ-5D-5L and changes in these assessments from preoperative baseline
- Pain (Groin, Thigh, and Buttock)
- Patient Satisfaction
- Post-op time when functional activities can be accomplished (return to work; self-care; etc.)
- Radiographic Outcomes (based upon: AP Hip, AP Pelvis, and Lateral)

- Length of hospital stay after index THA
- Re-hospitalizations during the study (including a specific summary of re-hospitalizations within 90 days)
- Narcotic drug usage throughout the study (patient reported)
- Complications (including a specific summary of complications within 90 days post-surgery)

5 Study Design

5.1 Study Design Summary

This is a post-market randomized, prospective, multi-center study with a planned analysis of 400 subjects (200 per treatment group). Up to 20 study sites will be approved to participate in this study. Each site is expected to enroll the number of subjects as outlined in their clinical trial agreement. It is anticipated that each site will enroll approximately 20 subjects per arm (40 subjects total). Reallocation of patients may occur to allow completion of study enrollment in a timely manner. Sites may replace Subjects that are screen failures and preoperative or intraoperative withdrawals to ensure adequate numbers for final analysis.

Competitive enrollment will be utilized and managed by the sponsor. The sponsor will communicate to each site regarding increased or decreased enrollment allotment and each site should anticipate enrolling 40 total subjects (20 per arm) unless it is communicated otherwise. Details regarding sample size are presented below in **Section 10.8.**

Each site will use the Pinnacle cup and the stem (Corail or Actis uncemented) that fit with their standard of care. The devices used in this study are available to all patients needing uncemented THA whether they choose to be a part of the study or not, since this is a post-market study.

5.2 Study Database

The study database has been validated in accordance with 21 CFR Part 11. Prior to being released for importation of study data, validation of the study level components will be conducted in accordance with approved user acceptance testing procedures. Access to this system will be controlled so that only authorized users will have the ability to enter into the system. The system is considered a closed system according to 21 CFR Part 11 Electronic Records; Electronic Signatures.

6 Radiographs

The radiographs collected for this study will be sent to Medical Metrics, Inc. (MMI) for third party review. This study will accept radiographs for the preoperative interval taken prior to the study Subject's participation in this study up to 180 days before surgery as long as the radiographs meet the three

protocol required views: Antero-Posterior (AP) Long Leg or AP Pelvis (bilateral), AP Hip (unilateral), and Lateral. Preoperatively, weight-bearing AP Pelvis and AP Hip and Modified Lauenstein views are preferred, but not required. The 180 day preoperative window is allowed in order to minimize a study subject's unnecessary exposure to radiation, therefore, standard of care views will be accepted preoperatively if imaging has already been acquired before the subject was consented for the study. For all post-operative intervals, weight-bearing AP Hip and AP Pelvis, and Lateral films are required. The Modified Lauenstein view is preferred postoperatively but a Lauenstein lateral or cross-table lateral view will be accepted in instances where the view cannot be collected due to subject positioning constraints. Further radiographic details will be available in the radiographic protocol separate to this document.

7 Subject Evaluations

This section details the pre-operative, operative, and post-operative management of Subjects. This study does not limit the procedures involved in the treatment of the subject (i.e. all medical care decisions related to the surgery are standard of care and at the discretion of the surgeon). The pre-operative, anesthesia, operative procedures, post-op care, and follow up are not research procedures, and therefore are not restricted by the study and are regardless of the research. This study will collect data from the standard of care medical treatments and requires the following research related activities: Subject self-assessments (Forgotten Joint Score, EQ-5D-5L, Hip Evaluation), Harris Hip Evaluation (if not already standard of care), preoperative planning details, radiographic evaluations, radiographic imaging (some study-required views might be outside site standard of care).

7.1 Pre-operative Evaluation (-180 Days to Date of Surgery)

The following data will be collected from the pre-operative evaluation:

- Informed Consent
- Study Visit (CRF detailing type of visit and subject status)
- Eligibility
- Randomization
- Demographics
- Targeted Medical History (self-reported by subject or within clinic notes)
- Height and Weight (Collected on Vital Signs CRF)
- Narcotic Drug Use (patient reported)
- Preoperative Hip Evaluation (HE1)
- Harris Hip Score
- Radiographs (AP Hip (unilateral), AP Pelvis (bilateral), and Lateral)
- EQ-5D-5L
- Preoperative Planning Details (planned inclination and anteversion, planned cup & stem size)
- **OPTIONAL:** Preoperative templates (used for planning cup position, cup & stem size)
  Note: The Sponsor is requesting submission of preoperative templates, to be included with the preoperative radiographs, if the surgeon/site templates per their standard of care. Templating is not a requirement for participation in the study
- Protocol Deviation Form (if needed)

- End of Study (Withdrawal) Case Report Form (if needed)

7.2 Operative and Perioperative Evaluation (Day 0 to Day of Discharge)

The following data will be collected from the operative and perioperative evaluations:

- Study Visit (CRF detailing type of visit and subject status)
- Operative Details
- Device Details
- Discharge Details
- Narcotic Drug Use (patient reported)
- Adverse Event Form (if needed)
- Protocol Deviation Form (if needed)
- Device Deficiency (if needed)
- End of Study (Withdrawal) Case Report Form (if needed)

7.3 Six Week Postoperative Evaluation (Day 14 – Day 60)

The following data will be collected from six-week postoperative evaluation:

- Study Visit (CRF detailing type of visit and subject status)
- Postoperative Hip Evaluation (HE2)
- Postoperative Hip Evaluation – Functional Outcomes (HE3*)
- Narcotic Drug Use (patient reported)
- Harris Hip Score
- Radiographs (AP Hip (unilateral), AP Pelvis (bilateral), and Lateral)
- EQ-5D-5L
- Forgotten Joint Score
- Adverse Event Form (if needed)
- Protocol Deviation Form (if needed)
- Device Deficiency (if needed)
- End of Study (Withdrawal) Case Report Form (if needed)

** The Functional Outcomes portion of the Hip Evaluation CRF (HE3) will be initially completed at the 6 week visit, and only questions that are marked as "still cannot do" or "still have not returned to work" will be addressed at subsequent study visits*

7.4 Twenty-Four Week Postoperative Evaluation (Day 61 to Day 200)

The following data will be collected from twelve-week postoperative evaluation:

- Study Visit (CRF detailing type of visit and subject status)
- Postoperative Hip Evaluation (HE2)
- Postoperative Hip Evaluation – Functional Outcomes (HE3*)
- Narcotic Drug Use (patient reported)
- Harris Hip Score
- Radiographs (AP Hip (unilateral), AP Pelvis (bilateral), and Lateral)
- EQ-5D-5L

- Forgotten Joint Score
- Adverse Event Form (if needed)
- Protocol Deviation Form (if needed)
- Device Deficiency (if needed)
- End of Study (Withdrawal) Case Report Form (required unless completed previously)

** The Functional Outcomes portion of the Hip Evaluation CRF (HE3) will be initially completed at the 6 week visit, and only questions that are marked as "still cannot do" or "still have not returned to work" will be addressed at subsequent study visits*

7.5 Study Completion

A study completion CRF should be completed for each subject for the following reasons (list may not be inclusive of all reasons for study withdrawal):

1) Subject withdraws consent

2) Subject has the cup and/or stem revised or removed

3) All data is entered onto the CRFs as completely as possible and the Subject completes study per protocol

4) Subject dies

5) Subject is lost to follow up

6) Subject is a screen failure after consenting as described in section 3.5

7) Subject is withdrawn by the Investigator

8 Adverse Events (AEs)

An adverse event (AE) is defined as an untoward medical occurrence, unintended disease or injury, or untoward clinical signs (or change or worsening of a pre-existing medical condition) in a patient, which may or may not have an association with the device. In addition, an adverse device effect is defined as "any untoward and unintended response to a medical device". Further types of AEs and definitions are located in **Table 8-1** below.

For this study, there are three types of events that will need to be reported via the Adverse Events (AE) eCRF:

1) Device Related AEs (see **Section 8.3** and **Figure 8-1** below)

2) Procedure Related AEs (see **Section 8.4** and **Figure 8-1** below)

3) Serious AEs (See **Table 8-1** and **Figure 8-1** below)

A record of each reportable adverse event, including details of the nature, onset, duration, severity, seriousness, relationship to the device, relationship to the operative procedure and outcome, will be made on an Adverse Events eCRF. Subjects must be questioned about any adverse event(s) at each subsequent encounter, whether a protocol scheduled follow up visit or not. The date that the site first became aware of the Subject's adverse event will also be documented (i.e., "site awareness date"). "Site awareness" is defined as the time when medical personnel and/or the site's study team, who are employed by or otherwise formally affiliated with the site (i.e., clinic and/or the hospital entity utilizing the same EMR system), obtain information about a reportable event.

AEs should be reported beginning from the start of surgery (*i.e.,* first incision) until Subject participation has ended (study completed, or consent withdrawn). When a Subject ends participation in the trial (either study completion or consent withdrawal) all open AE outcomes must be designated as "Recovered/Resolved with no residual effects", "Recovered/Resolved with residual effects", "Ongoing", "Death", or "Unknown" providing a resolution date or ongoing designation.

8.1 Anticipated Adverse Events / Non-Reportable Adverse Events (to Sponsor ONLY)

There are particular immediate non-serious post-operative events that are changes from the baseline condition of the Subject but are expected events resulting from surgery. For the purposes of this protocol these are referred to as Anticipated Adverse Events and are listed in **Exhibit A**. If these events occur, they should be recorded in the Subject's medical record, but these should NOT be reported as AEs in the eCRF or to the Sponsor. However, if these events occur with a severity deemed above "expected/normal" or meet the criteria of "serious", they should be reported to the Sponsor by completing an AE eCRF in the study database.

Table 8-1 Definitions of Adverse Event (AE) Types, Device Deficiency

Table 8-1 Definitions of Adverse Event (AE) Types, Device Deficiency	
Adverse Event (AE)	AE is defined as an untoward medical occurrence, unintended disease or injury, or untoward clinical signs (or change or worsening of a pre-existing medical condition) in a patient, which may or may not have an association with the device. All reported AEs (defined in Section 8) will be submitted to the DePuy Synthes Complaint Handling Unit, via electronic reporting from the AE eCRF, who will complete all reporting determinations.
Serious Adverse Event (SAE)	SAE is defined as an Adverse Event, regardless of relationship to device or procedure, that: • led to a death,

	• led to a serious deterioration in health that either: ○ resulted in a life-threatening illness or injury, or ○ resulted in a permanent impairment of a body structure or a body function, or ○ required inpatient hospitalization or prolongation of existing hospitalization, or ○ resulted in 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. • Other serious important medical events. Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. *Examples of procedure related serious AEs (SAEs) may include: stiffness requiring manipulation of the hip under anesthesia, dislocation of hip requiring closed reduction, Deep Vein Thrombosis (DVT) without hospitalization.* *Examples of device related SAEs may include radiolucent lines around the femoral component or joint dislocation.* **All serious adverse events should be reported to the Sponsor by completing an AE eCRF as quickly as possible – not to exceed 72 hours after the investigator or site becomes aware of the event**
Device Deficiencies	Are defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability safety or performance. Device deficiencies include malfunctions, use errors and inadequate labeling. Upon identification of device deficiencies, the investigator should complete a device deficiency eCRF, institute appropriate therapeutic and follow-up measures in accordance with good medical practice and notify the IRB as applicable. The Investigator must document follow-up treatment of any resulting AE (if applicable) and the Sponsor will report the event through its applicable complaint reporting channels.

8.2 Definition of Severity

An adverse event (AE) or an adverse device effect (ADE) may be:

- **Mild**: Easily tolerated and transient in nature with minimal or no impairment of normal activity)
- **Moderate**: Poorly tolerated, sustained and interferes with normal activity and requires medical attention
- **Severe**: Poorly tolerated, requires intervention and significantly affects activities of daily life; or places the Subject at immediate risk or harm.

8.3 Device or Procedure Related

The determination whether the AE is related to the device or procedure will be based upon whether a causal relationship between the device or procedure and the AE is at least a reasonable possibility, *i.e.* the relationship cannot be ruled out. A causal relationship cannot be ruled out if, in the medical judgment of the Investigator, the effect follows a reasonable temporal association with the use of the device and/or is confirmed by the improvement of the effect upon discontinuation of the clinical use of the device, and/or the effect is not reasonably explained by the Subject's clinical state.

Relationship to study device ***or*** procedure should both be rated as follows, "*Is this event related to the study device (or procedure)?*" options are: Definitely, Probably, Possibly, Remote possibility or Definitely not. All adverse events (medical change from baseline) experienced by a subject should be noted in their source documents with these relationships to document the sites' determination.

8.4 Worsening Adverse Events

For a worsening AE, the original AE should be reported as resolved on the AE eCRF and an additional AE eCRF should be completed for the new Severity. Examples of this exercise are provided in the study tool "Case Report Form Completion Guidelines", provided separately. An example is that if a "Mild" AE of pain with no treatment exacerbates to a "Moderate" AE of pain with a treatment of an injection, a study site must resolve the "Mild" AE and report the worsening on an additional AE eCRF. The original 'Mild" AE will **not** be counted twice; however, each AE will be counted individually – as in one Mild AE and one Moderate AE.

8.5 Safety Reporting Timelines

Each reportable adverse event should be forwarded to the Sponsor via submission of the AE eCRF. It is expected that each adverse event will be submitted when the site becomes aware of the event as defined in Section 8. See the table below for the maximum timelines for reporting:

AE Type	Reporting Timelines
Serious Adverse Events (SAEs)	Completion of an AE eCRF as soon as the site becomes aware, but **not longer than 72 hours** after date of awareness
All other non-serious AEs that are reportable per this protocol	Submission of AE eCRF **within 2 weeks** of date of awareness

8.6 Exacerbation of Pre-existing Medical Conditions

Pre-existing medical conditions or symptoms reported prior to device implantation are to be recorded as history and not to be recorded as AEs (e.g., History of Asthma or existing osteoarthritis in contralateral knee would be recorded on the Subject History eCRF). In the event there is an exacerbation of the pre-existing medical condition or symptoms that meets the definition of serious, then an AE must be reported (e.g. exacerbation of existing Asthma that requires hospitalization).

8.7 Determination of Anticipated/Unanticipated

The PI is responsible for determining whether an AE is **anticipated** or **unanticipated**. This determination is based on whether the severity, type and frequency of the AE is consistent with the Instructions for Use (IFU), in the opinion of the PI. Note that since THA is a routine elective procedure, the vast majority of adverse events are anticipated and included in the IFU.

When a PI classifies an AE as unanticipated, the Sponsor will a review the determination based on the reported event and in consideration of the IFU and internal risk reports. In the event that the Sponsor has a different opinion on the determination a query will be generated. When there is a discrepancy on the determination between the site and the Sponsor, both opinions will be recorded and reported as required to the relevant IRB.

8.8 Minimization of Risks

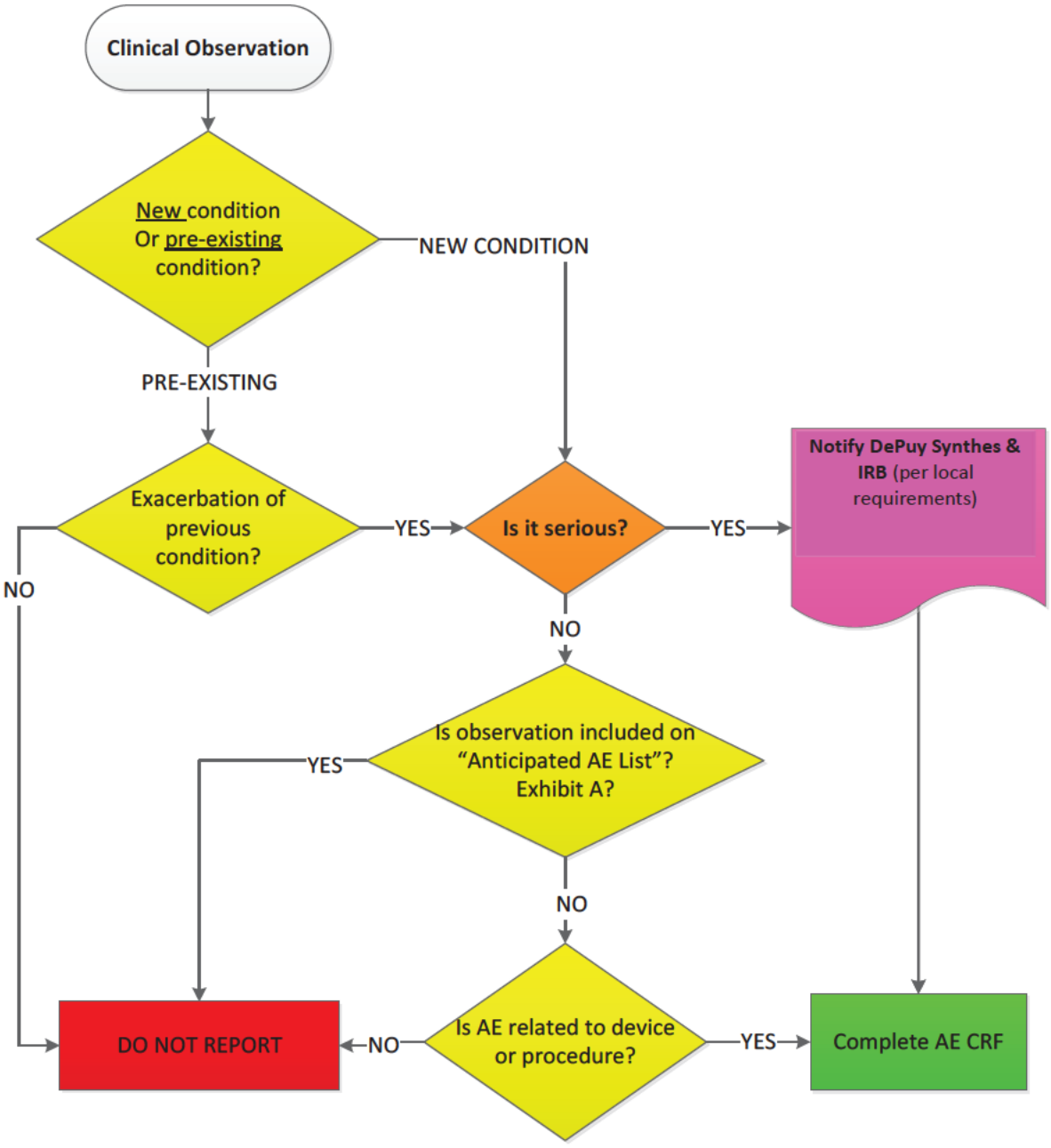
The Sponsor will further minimize the identified and/or emergent risks throughout the study by reviewing the reported complications and adverse effects. Adverse events will be reviewed and reported as applicable based on IRB and regulatory requirements. Based upon an evaluation of such events, the Sponsor may either amend the investigational plan or terminate the investigation to protect the rights, safety and welfare of the study Subjects.

Should an IRB decide to suspend or withdraw its approval for a PI to conduct the study at that institution, based on unacceptable risks to the study Subjects, the study Sponsor will notify all reviewing IRBs, and PIs of this action. To further minimize risks, any new information obtained during the course of the study relating to unanticipated adverse findings will be provided to all Subjects, PIs, and IRBs.

The study has been designed to minimize the number of Subjects yet provide sufficient numbers of Subjects for valid scientific analysis of the compiled study data. The study design, the procedures for monitoring and the documentation, reporting and evaluation of the results will further control risks.

Figure 8-1: AE Reporting Flowchart

The AE Reporting flowchart illustrates a series of questions a site must consider when determining whether a clinical observation must be reported, and which AE's do not need to be reported for this CIP per the required timelines as defined in Section 8.5.



9 Informed Consent Process

In compliance with ISO 14155 and 21CFR50, no Subject shall be enrolled in an investigation without provision of adequate informed consent. The Principal Investigator is responsible for ensuring that no Subject is included in the study without adequate informed consent being provided. Failure to obtain and properly document this process is in violation of 21CFR Part 50, ISO 14155, the Declaration of Helsinki, and this study protocol.

All Informed Patient Consent (IPC) documents must have favorable opinion of the IRB. Many institutions request modification of the IPC to satisfy specific institutional requirements. The use of a modified or unique IPC is permitted provided that all applicable regulatory requirements are met and the document is approved by the Sponsor before use.

Subjects who agree to participate in the study will complete an IRB approved IPC document that documents his or her willingness to take part in this study. Each potential Subject will have the nature and the purpose of this study explained to him or her by the Principal Investigator (PI) or another delegated member of the investigative team at the study Site. The PI or designee will explain the following features of the study to the patient thoroughly and will offer to answer any questions the patient may have.

- The purpose of the study
- The potential risks or adverse events that are posed by their treatment
- The potential risks or adverse events related to study participation
- Alternative procedures/treatments available to the Subject
- Requirements of the study follow-up visits
- All of the Subject's rights as a participant in the clinical investigation

Consent must be given by the Subject and documented on an Informed Patient Consent Document in the primary language of the Subject. A signed copy of the IPC is to be provided to the Subject. An IPC must be obtained for all Subjects *prior* to the Subject completing any study-specific assessments or procedures that are not standard of care. *A study Subject is considered enrolled in the study once they have signed the IPC.*

No dates should be pre-populated or completed by someone other than the person providing the signature.

Subjects will be made aware that their personal data will be collected and processed in accordance with data protection legislation including Health Insurance Portability and Accountability Act of 1996 (HIPAA). The release of Personal Health Information (PHI) for the purpose of this clinical investigation will be included in the informed patient consent unless site policies require this release be maintained in a

separate document. Results from this clinical investigation may be published, however, subject confidentiality will be maintained at all times and it will not be possible to identify them from any data presented.

Any data collected for subjects for whom consent cannot be recognized will not be reported. In such a case the subject will be excluded from all analysis sets (enrolled, safety, per protocol).

10 Statistical Methodology

Statistical analysis will be performed using SAS®software version 9.4 or higher. Any further software that may be necessary will be described in the final study report.

10.1 Study Design

This is a post-market 1:1 randomized, prospective, multi-center study with a planned analysis of 400 subjects (200 per treatment group). Details regarding the number of study sites and enrollment allocation within each site are presented above in **Section 5.1**. Details regarding sample size are presented below in **Section 10.8.**

10.2 Treatment Assignment

See section 3.4 for the assignment of planned treatment.

Treatment received is defined as KINCISE if the KINCISE device was used for femoral broaching, MALLET otherwise.

10.3 Levels of Significance

The level of significance for the hypotheses related to the non-inferiority/superiority tests of the primary endpoint and for the hypotheses associated with the secondary endpoints is defined is sections 10.9.2 and 10.9.3.

Unless otherwise stated, all other confidence intervals and p-values will be provided for exploratory analyses to facilitate clinical judgement, with no adjustment of significance levels; Confidence intervals will be 2-sided 95% confidence intervals.

10.4 Handling of Missing Data

Missing data will be assumed missing at random. Actual subject data which is collected will be utilized in analyses to determine the outcome of the analyses for all endpoints.

10.5 Primary and Secondary Endpoints

10.5.1 Primary Endpoint

The primary endpoint analysis is to demonstrate that femoral broaching time (in minutes) with KINCISE is non-inferior to femoral broaching time with manual instruments (not using KINCISE) under a non-inferiority margin of 1.25 minutes.

Hypotheses for this non-inferiority analysis are as follows:

- Null Hypothesis: H_0: $\mu_I \geq \mu_C + 1.25$
- Alternative Hypothesis: H_A: $\mu_I < \mu_C + 1.25$

whereμ_I and μ_C are mean femoral broaching times with and without KINCISE, respectively, and 1.25 is the NI margin. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided upper 95% confidence limit for the $\mu_I - \mu_C$ difference (based upon a 2-sample t-test) is less than 1.25. The study will be deemed to be successful if this analysis demonstrates non-inferiority of femoral broaching time.

If non-inferiority is successfully demonstrated, then a test for superiority will be conducted to assess if femoral broaching time with KINCISE is less than femoral broaching time without KINCISE with statistical significance (1-tailed t-test with 5% alpha).

10.5.2 Secondary Endpoints

If the primary endpoint analysis successfully demonstrates non-inferiority of femoral broaching time, regardless of whether the above test of superiority was successful or not, then the following three secondary endpoint analyses will be conducted under a gatekeeping strategy, in this specified order, where testing is performed in sequence and continues until an alternative hypothesis is not rejected or all hypotheses have been tested, each with a 1-sided alpha of 0.05:

- A non-inferiority test of skin-to-skin OR time will be conducted with a non-inferiority margin of 3.75 minutes, using a 2-sample t-test
    - Null Hypothesis: H_0: $\mu_I \geq \mu_C + 3.75$
    - Alternative Hypothesis: H_A: $\mu_I < \mu_C + 3.75$
    - where μ_I and μ_C are mean skin-to-skin OR times with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided upper 95% confidence limit for the $\mu_I - \mu_C$ difference (based upon a 2-sample t-test) is less than 3.75.
- A non-inferiority test of the percent of subjects with acetabular cup abduction angle within +/- 10 degrees of plan under a NI margin of 10%
    - Null Hypothesis: H_0: $P_I \leq P_C - 10\%$
    - Alternative Hypothesis: H_A: $P_I > P_C - 10\%$

- where P_I and P_C are the percentages of subjects with acetabular cup abduction angle within 10% of plan with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided lower 95% confidence limit for the $P_I - P_C$ difference (based upon a normal approximation method) is greater than -10%.

- A non-inferiority test of the percent of subjects with acetabular cup version angle within +/- 10 degrees of plan under a NI margin of 10%
  - Null Hypothesis: H_0: $P_I \leq P_C - 10\%$
  - Alternative Hypothesis: H_A: $P_I > P_C - 10\%$
  - where P_I and P_C are the percentages of subjects with acetabular cup version angle within 10% of plan with and without KINCISE, respectively. The null hypothesis will be rejected and non-inferiority will be concluded if the 1-sided lower 95% confidence limit for the $P_I - P_C$ difference (based upon a normal approximation method) is greater than -10%.

In addition, the following secondary endpoints do not have prospectively planned hypotheses; these will be summarized for both treatment groups:

- Harris Hip Score (HHS) and HHS change from preoperative baseline
- Forgotten Joint Score (FJS) and FJS change from 6-week postoperative baseline
- EQ-5D-5L and changes in these assessments from preoperative baseline
- Pain (Groin, Thigh, and Buttock)
- Patient Satisfaction
- Post-op time when functional activities can be accomplished (return to work; self-care; etc.)
- Radiographic Outcomes (based upon: AP Hip, AP Pelvis, and Lateral)
- Length of hospital stay after index THA
- Re-hospitalizations during the study (including a specific summary of re-hospitalizations within 90 days)
- Narcotic drug usage throughout the study (patient reported)
- Complications (including a specific summary of complications within 90 days post-surgery)

10.6 Analysis Sets

Table 10-1 Analysis Populations

Population	Subjects Included
Enrolled Population	The Enrolled population set will consist of all subjects who sign the informed consent document.
Safety Population	The Safety Population set will consist of all subjects in the Enrolled population set for whom treatment was attempted, according to the actual treatment received.
Per Protocol Population	The Per Protocol Population set will consist of all subjects in the Enrolled population set who successfully received the planned treatment, who were seen at least once at a post-operative visit, and who did not have any protocol deviations which were prospectively determined to potentially have influence on the scientific validity of the data (such as inclusion/exclusion criteria).

10.8 Sample Size Justification

Primary endpoint NI analysis: Based upon input from key opinion leaders (KOLs) and data from other studies, typical femoral broaching time with manual instruments is anticipated to have a range of 5 to 15 minutes, which implies a standard deviation of approximately 2.5 minutes (1/4 of the range). Moreover, KOLs suggest that a difference of 10 minutes in femoral broaching time (increase for a single patient) is clinically meaningful. The non-inferiority margin of 1.25 minutes was established because it is ½ of the anticipated standard deviation and is much less than a clinically meaningful difference. Under a 1-sided test with 5% alpha, a sample size of N=88 per group would be sufficient to demonstrate non-inferiority with 95% power. A sample of size N=200 per group (N=400 total) was chosen as feasible by the sponsor and desirable for providing further data for both KINCISE and Anterior Advantage; this sample size would provide more than 99% power to demonstrate non-inferiority for the primary endpoint analysis.

Primary endpoint supplemental superiority analysis: It is not known if there will be a true difference in means between groups. However, if there is a true difference of 1 minute between group means (lower time favoring KINCISE), and assuming an SD as stated above (2.5 minutes), then a sample of N=200 per group (N=400 total) would provide approximately 99% power to demonstrate superiority.

Secondary endpoint analyses:

- Non-inferiority of skin-to-skin OR time

  Based upon input from KOLs and data from other studies, skin-to-skin OR time is anticipated to have a typical range from 60 to 90 minutes, which implies a standard deviation of approximately 7.5 minutes (1/4 of the range). The non-inferiority margin of 3.75 minutes was established because it is ½ of the anticipated standard deviation and is much less than the 10 minute clinically meaningful difference in femoral broaching time (a subset of skin-to-skin OR time). Under a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with greater than 99% power.

- Non-inferiority of optimal acetabular cup abduction

  The percent of subjects within +/- 10 degrees of planned cup abduction for an anterior approach (AA) is anticipated to be between 90% and 95% (based on studies presented by Hamilton[12] and Rathod[13], respectively). These are a clinical improvement from percentages exhibited with a posterior approach (PA), which were 79% and 86% in [1] and [2], respectively. A NI margin of 10% was chosen because it is less than the improvement from PA to AA observed by Hamilton[12] and Rathod[13]. With this margin and a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with approximately 95% power.

- Non-inferiority of optimal acetabular cup abduction

  The percent of subjects within +/- 10 degrees of planned cup version for an anterior approach (AA) is anticipated to be between 91% and 92% (based on studies by Rathod[13] and Hamilton[12], respectively). These are a clinical improvement from percentages exhibited with a posterior approach (PA), which were 64% and 77% in [1] and [2], respectively. A NI margin

of 10% was chosen because it is less than the improvement from PA to AA observed by Hamilton[12] and Rathod[13]. With this margin and a 1-sided test with 5% alpha, a sample size of N=200 per group would be sufficient to demonstrate non-inferiority with approximately 95% power.

In summary, with a sample size of N=400 (200 with KINCISE; 200 without KINCISE), the anticipated overall likelihood of demonstrating the primary endpoint non-inferiority analysis, followed by the three stated secondary endpoint non-inferiority analyses in the specified gate-keeping order, is at least (99%)(99%)(95%)(95%) ≈ 88%.

10.9 Analysis Plan

Standard descriptive summaries for continuous data include the number of observations with data, number of observations with missing data, mean, standard deviation, median, minimum, and maximum values. For categorical data, the count (numerator), denominator and percent will be provided. Percentages will be based on the number of subjects without missing data, unless indicated otherwise.

Datapoints will be reported based on the visit date reported by the investigator. In the case where there are multiple visits reported within the same interval, the latest visit (most proximal to date of surgery) will be used for the preoperative timepoint, and the earliest visit will be used for the 6-week timepoint, and the latest (furthest from date of surgery) for the 24-week timepoint. If data is reported before the preoperative window (before -180 days pre-surgery) or after the close of the 24-week window (after 200 days post-surgery), these data will be removed from analysis and a separate analysis will report on the number of such visits.

10.9.1 Subject Accounting and Disposition

A subject accounting table and subject disposition table will present the count of subjects by site and overall for all population sets.

10.9.2 Demographic and Procedure Characteristics

All demographic characteristics, surgical, and immediate post-operative details will be summarized for both the Safety Population and the Per Protocol Population.

10.9.3 Primary Endpoint

The primary endpoint analyses, described in section 10.5.1, will be performed on the Per Protocol Population set. The primary endpoint will be summarized as a continuous endpoint for both treatments. The difference in means $\mu_I - \mu_C$ will also be summarized as a continuous endpoint. Its 1-sided upper 95% confidence limit and the p-value for the test of non-inferiority with a margin of 1.25 based on a 2-sample t-test will be produced. If non-inferiority is demonstrated, i.e. the p-value is < 0.05 then the test of superiority will proceed, and its p-value will be produced.

10.9.4 Secondary Endpoints

All secondary endpoint analyses will be performed on the Per Protocol Population.

Skin-to-skin OR time in minutes will be summarized as a continuous endpoint for both treatments. The difference in means $\mu_I - \mu_C$ will also be summarized as a continuous endpoint. Its 1-sided upper 95% confidence limit and the p-value for the test of non-inferiority with a margin of 3.75 based on a 2-sample t-test will be produced if the alternative hypothesis of non-inferiority of the primary endpoint is rejected.

The difference between acetabular cup abduction angle and plan for each subject will be summarized as a continuous endpoint for both treatments. The proportion of subjects with acetabular cup abduction angle within 10% of plan will be summarized as a categorical endpoint for both treatments. The difference in proportions $P_I - P_C$ will also be summarized as a categorical endpoint. Its 1-sided lower 95% confidence limit and the p-value for the test of non-inferiority with a margin of 10% based upon a normal approximation method will be produced if the alternative hypothesis of non-inferiority of skin-to-skin OR time is rejected.

The difference between acetabular cup version angle and plan for each subject will be summarized as a continuous endpoint for both treatments. The proportion of subjects with acetabular cup version angle within 10% of plan will be summarized as a categorical endpoint for both treatments. The difference in proportions $P_I - P_C$ will also be summarized as a categorical endpoint. Its 1-sided lower 95% confidence limit and the p-value for the test of non-inferiority with a margin of 10% based upon a normal approximation method will be produced if the alternative hypothesis of non-inferiority of acetabular cup abduction angle within 10% of plan is rejected.

With no prospectively planned hypotheses, the following secondary endpoints will be summarized at all visits with available data for both treatments as continuous variables:

- The Harris Hip Score (HHS) and change from baseline HHS
- Forgotten Joint Score (FJS) and change from 6-week postoperative FJS
- EQ-5D-5L and change from baseline
- Pain (Groin, Thigh, and Buttock)
- Patient Satisfaction
- Radiographic Outcomes (based upon: AP Hip, AP Pelvis, and Lateral)
- Length of hospital stay after index THA

With no prospectively planned hypotheses, the following secondary endpoints will be summarized at all visits with available data for both treatments as categorical variables:

- Post-op time when functional activities can be accomplished (return to work; self-care; etc.)
- Narcotic drug usage throughout the study (patient reported)

10.9.5 Safety Analyses

All safety analyses will be performed on the Safety Population set.

All Adverse Events (AE) from the start of device placement until subject finishes participation in the study will be summarized with frequencies, number of subjects with at least one AE, and percentages for the following categories: Overall, SAE, death, device and procedure related. AEs will also be summarized by Preferred Term within System Organ Class for overall for all reported AEs as well as for the subset of SAEs.

Re-hospitalizations during the study within 90 days post-op and complications within 90 days post-op will be summarized.

10.10 Interim Analysis

There are no planned interim analyses for the purpose of stopping the study early. However, some statistical analyses may be performed for conference presentations or abstracts prior to the primary endpoint being reached.

11 Data Management

Electronic Case Report Forms (eCRFs) entered into an electronic data capture (EDC) system will be used to collect all Subject data once a Subject is enrolled in the study. Study sites will be asked to enter Subject data into the eCRFs via the EDC web-based database portal promptly after each subject is enrolled.

For all Subjects, detailed information related to the primary diagnosis, anesthesia type and time, and surgical exposure (*e.g.,* anterior approach), and other surgical variables will be recorded on the Operative Details eCRF. Product code details for each implant and study article (KINCISE adapters as applicable) used during the procedure must be recorded on the Device Log eCRF.

Data collected during the study for each Subject will be maintained as accurately and completely as possible with entries into an EDC system provided by DePuy Synthes. The personal data recorded on all documents and within the EDC system will be regarded as confidential. The Investigator will be responsible for the timing, completeness and accuracy of the details entered within the EDC system. All data entered in the database must have source documents in the Subject's medical records.

The Investigator should retain copies of all documents pertaining to this study (including source documentation, the informed consent document and any other documents to identify the Subjects) for at least two years after this clinical investigation is completed. In addition, if the Investigator moves/retires, etc., she/he should provide DePuy Synthes with the name and address of the person who will be responsible for the Subjects' study related records.

12 Study Implants

The Pinnacle Hip Solutions® (Pinnacle cup) system was first launched in 2000. Multiple configurations are now available (see Table 12-1 below).

Table 12-1 Pinnacle Hip System Details

Cup Style	Image	Description
100		• POROCOAT®, DUOFIX® or GRIPTION® coating • Available in sizes 48-66 mm (44 & 46mm available in GRIPTION)
Sector		• Three screw holes for optional adjunct fixation - screw hole pattern allows screw access to the ilium and posterior column • POROCOAT, DUOFIX or GRIPTION coating • Available in sizes 48-66 mm
300		• Three porous-coated spikes enhance initial fixation - spike length is designed to engage the dome of the acetabulum as the rim of the cup engages the periphery of the acetabulum to enhance directional stability of the cup upon impaction • POROCOAT coating • Available in sizes 48-66 mm
Multihole		• 8 -12 screw holes, depending on cup size, for optional adjunct fixation (for more demanding cases or revisions) • GRIPTION coating • Available in sizes 48-72 mm
Bantam		• For smaller patients or acetabular dimensions, dysplastic acetabuli (DDH) • POROCOAT or GRIPTION coating • Sizes 38-46 mm

The CORAIL® Stem was first implanted in 1986 by the ARTRO Group in France. Combining basic design features, including shape, surface finish and extensive hydroxyapatite coating, with a simple compaction broach-only surgical technique, the CORAIL® Stem has demonstrated excellent long-term results.

The Actis® medial collared DUOFIX® hip stem is manufactured from forged titanium alloy (Ti-6A1-4V) and has a sintered commercially pure titanium bead porous coating (POROCOAT®), and a thin layer of plasma-sprayed hydroxyapatite (HA) coating.

Figure 12-1 Corail® & Actis Stem

Please refer to **Exhibit B** for the CORAIL and Actis stem product codes that can be used in this study.

13 Deviations and Non-compliance Handling

The investigator must not deviate from this protocol. Protocol deviations will be reported to the IRB as applicable per their requirements.

14 Ethical Principles

This clinical investigation shall be conducted in accordance with applicable local laws and regulations and the ethical principles that have their origin in the most recent version of the Declaration of Helsinki. The most recent version of the Declaration of Helsinki can be found here: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

15 Principal Investigator Responsibilities

An Investigator's responsibilities in conducting clinical investigations of a medical device are described below. Additionally, a signed Statement of Investigator (SOI) form will be in place prior to consent of the first subject into the study.

In conducting this medical device clinical investigation, the Investigator is responsible for:

1) Ensuring that a clinical investigation is conducted according to applicable regulations for clinical investigations of medical devices, the signed agreement, and the investigational plan; and,
2) Protecting the rights, safety, and welfare of subjects under the investigator's care. An Investigator's responsibilities in conducting clinical investigations of a medical device are described in detail below.

15.1 Institutional Review Board (IRB) Approval

Each Investigator must obtain IRB approval prior to the consent of the first Subject; no study-related procedures can occur without the approval and oversight of an IRB.

All Principal Investigators must submit for initial review a copy of the clinical investigational plan (CIP) and a sample Informed Patient Consent Document (IPC) to their institution's IRB. Additionally, patient completed forms (EQ-5D-5L, FJS-12, Hip Evaluation) should be submitted for review. Initial approval must be documented; originals of correspondence and approvals are to be filed by the Investigator and copies forwarded to the Sponsor.

Continuing review and any other additional required submissions will be forwarded for IRB review according to their policies and procedures. Approval or acknowledgement must be documented; originals of correspondence and approvals are to be filed by the Investigator and copies forwarded to the Sponsor.

15.2 Informed Patient Consent (IPC)

The Principal Investigator is responsible for ensuring that no Subject is included in the study without adequate informed consent being provided. Source documents must be maintained, evidencing informed consent was collected prior to participation in the study. Failure to obtain or properly document this process is in violation of the ISO 14155, 21CFR50, the Declaration of Helsinki and this study protocol.

See descriptions of the Informed Consent process in **Section 9**, Informed Patient Consent Process. Each subject is entitled to withdraw from this clinical investigation for any reason without obligation and/or prejudice to further treatment.

The Investigator will clearly document the date and reason(s) for the subject's withdrawal from this clinical investigation, and submit the appropriate form(s) to DePuy Synthes.

15.3 Source Documentation

The Investigator will maintain original source documentation records of each Subject's case history. Case histories include the source worksheets, patient reported outcome measures (PROMs), and medical records, including progress notes, hospital charts, nurses' notes, etc.

Records shall include:

- Documents evidencing informed consent
- All relevant observations concerning adverse events
- Subject history of each Subject upon entering the study
- Information on the condition of the Subject during the course of the study.

15.4 Electronic Case Report Form (eCRF) Completion

Electronic Case Report Forms (eCRFs) in an electronic data collection (EDC) system will be used to collect all Subject data once a Subject is enrolled in the study.

Detailed description of the eCRF components and eCRF completion guidelines are included in the User Instructions available in the MediData Rave System and eCRF Completion Instructions (CCIs), which will be provided to the Investigators and applicable site staff to aid in data entry in the EDC system. The respective eCRFs should be fully completed for each Subject and signed electronically by the Investigator.

15.5 Clinical Investigation Plan (CIP) Adherence

The Investigator must not deviate from the investigational plan. The Investigator will notify the Sponsor, and the reviewing IRB as applicable of any deviation from the investigational plan. The Sponsor will evaluate non-compliance with the CIP to determine appropriate corrective action(s), if applicable. If compliance cannot be secured, the continued non-compliance could result in site suspension or termination.

15.6 Clinical Investigation Plan (CIP) Amendments

Applicable IRB approvals will be obtained prior to implementation of changes in the Clinical Investigational Plan that may affect the scientific soundness of the investigation or the rights, safety or welfare of study subjects. Administrative changes must also be submitted to the reviewing IRB.

15.7 Investigator Reporting Responsibilities

The Principal Investigator is responsible for submitting complete, accurate and timely reports as described below:

Table 15-1 Principal Investigator Reporting Responsibilities

Principal Investigator Reporting Responsibilities	
Report	**Description**
Withdrawal of IRB Approval	The Investigator will notify the Sponsor of a withdrawal of approval by the reviewing IRB of the Investigator's part in an investigation **within 5 working days**.
Reports of Deviations from the Clinical Investigational Plan (CIP)	Investigator or delegate will report deviations from the CIP to the Sponsor via the EDC system, and to the reviewing IRB (as applicable per the IRB requirements).
Other	The Investigator will, **upon request** by a reviewing IRB, provide accurate, complete, and current information about any aspect of the investigation.
Serious Adverse Event (SAE defined in **Section 8.1**)	The Investigator will notify the Sponsor, and their reviewing IRBs as applicable, of all SAEs upon awareness of the event (see **section 8.5** for reporting timelines)
All other Adverse Events (see **Section 8** for more detail)	The investigator will submit AEs upon awareness of the event (see **section 8.5** for reporting timelines)

15.8 Investigator Site Files (ISF or Regulatory Binder)

Each Investigator must maintain accurate, complete, and current information about all aspects of this clinical investigation. This includes documentation relating to the Investigator's participation, Subject information (as applicable), and all correspondence relating to the clinical investigation. Correspondence consists of, but is not limited to, written and verbal correspondence with other participating Investigators, the reviewing IRB, and the Sponsor.

The Investigator will maintain all records relating to the clinical investigation for a minimum period of 2 years after the clinical investigation is completed.

16 Sponsor Obligations

16.1 IRB Approval

Each Investigator must obtain IRB approval prior to consent of the first Subject. Each Investigator must also maintain continuous approval. Documentation of initial approval, subsequent renewals and IRB closure must be provided to the Sponsor and filed on site in the Investigator Site File (ISF). Additionally, amendments to the protocol will be submitted for review before implementation, and copies of the submissions and approvals provided to the Sponsor.

The Sponsor will maintain copies of all site IRB documentation in the Trial Master File.

16.2 Investigator Training, Site Initiation Visit

Prior to enrolling Subjects in this study, the Investigator and/or appropriate Site personnel will be trained in general aspects of study administration, content and manner of administration of the Subject questionnaires, all procedures in the protocol, and the procedure for electronic data acquisition and radiographic transmission.

Training will be done through a combination of teleconferences, Web-Ex conferences and on-site training as appropriate.

16.3 Sponsor Reporting Responsibilities

The devices utilized in this study are not investigational and therefore reporting to regulatory agencies is not required.

Additional reports the Sponsor is responsible for preparing and submitting are described below:

Table 16-1 Sponsor Reporting Responsibilities

Sponsor Reporting Responsibilities	
Report	**Description**
Withdrawal of IRB approval	The Sponsor shall notify all reviewing IRBs and participating Investigators of any withdrawal of approval of the investigation by a reviewing IRB within 5 working days after receipt of notice.
Other	The Sponsor will, upon request by a reviewing IRB provide accurate, complete, and current information about any aspect of the investigation.

16.4 Study Monitoring

Sponsor oversight will be maintained per Sponsor policies and procedures. Monitoring procedures and frequency will be conducted throughout the course of the study according to the Clinical Monitoring Plan. Qualified site study personnel are expected to meet with the clinical monitor to resolve queries and review action items at any onsite monitoring visit.

During the visit, the Sponsor and authorized Sponsor representatives shall be given access to all study records, to include study Subject medical records.

16.5 Sponsor Study Termination

The Sponsor may prematurely terminate or suspend the clinical study as a whole or at an individual investigational site for significant and documented reasons. Reasons for premature termination or suspension include, but are not limited to safety, inadequate recruitment, Principal Investigator issues, device related problems, alignment with business strategy, or administrative issues.

If suspicion of an unacceptable risk to Subjects arises during the clinical study, or when instructed by an IRB or a Regulatory Authority, the Sponsor shall suspend the clinical study at all active sites while the risk is assessed. The Sponsor shall terminate the clinical study if an unacceptable risk is confirmed, or resume the clinical study following appropriate communication and approval from the IRB and a Regulatory Authority as required.

In terminating the clinical study, the Sponsor and the Principal Investigator will assure that adequate consideration is given to the protection of the subjects' interests. All documentation is archived and the appropriate bodies such as the IRB and any Regulatory Authorities are informed as appropriate.

17 Publication Plan

All manuscripts containing data obtained from this clinical investigation will be reviewed and approved by the Sponsor, and each author, prior to any submission. The current and applicable Johnson & Johnson Medical Device & Diagnostic (MD&D) Publication Policy (J&J Publication Policy) will be followed. Publication will also be managed in accordance with applicable laws and regulations.

DePuy Synthes will require a written agreement for any external author(s) prior to initiating any publication. All authors must disclose financial or personal affiliations that could be considered a conflict of interest.

18 Study Summary Statement

This post-market randomized, controlled, multicenter study has been developed to compare the Anterior Advantage Approach with and without use of KINCISE. Data will be collected from the preoperative, operative, and 6-week and 24-week postoperative time points.

EXHIBIT A – Anticipated Adverse Events

In addition to the information provided in the Instructions for Use included with the packaging for all implants, the following adverse events are anticipated. **Assuming the following events are consistent with the normal postoperative course and do not meet the criteria of "serious", then they do NOT have to be reported as Adverse Events.**

Up to 24 Hours Postoperative	
Genitourinary	• Urinary retention
Cardiovascular	• Hypotension, not requiring treatment • Hypertension, not requiring treatment • Dysrhythmia (resolving within 36 hrs post-op)
Central Nervous System	• Incisional pain • Post-op consequences of narcotics use • Fatigue
Integumentary	• Surgical site ecchymosis • Sanguinous / sero-sanguinous drainage from incision • Venous congestion without thrombosis (foot swelling alleviated when lower limb is raised)
Constitutional	• Elevated temperature (no greater than 101°F)
Prior to Discharge	
Haematological	Changes in lab values not resulting in clinical symptomatology (Electrolytes, CBC, BS, PT/ PTT) Anemia, not requiring treatment
Gastrointestinal	Transitory: ○ Nausea ○ Vomiting ○ Constipation ○ Diarrhea
Central Nervous System	Headache Disorientation Confusion Dizziness Incisional /operative site pain
Respiratory	Atelectasis not requiring treatment
Integumentary	Foot Swelling not requiring intervention Surgical site ecchymosis Sanguinous / sero-sanguinous drainage from incision Skin blisters secondary to tape • Suture granuloma not involving cellulitis or deeper infection ("spitting suture", abscess suture)
Constitutional	Elevated temperature (no greater than 101°F)

If you have any questions about potential adverse events or adverse event reporting, then please contact DePuy Clinical Research.

EXIBIT B – DEVICE PRODUCT CODES

Table B-1: Pinnacle Hip System Product Codes






Size	100 Series POROCOAT Coating	100 Series GRIPTION® Porous Coating	100 Series DUOFIX® HA Coating	Sector POROCOAT Coating	Sector GRIPTION Coating	Sector DUOFIX Coating
44 mm	N/A	1217-31-044	N/A	N/A	N/A	N/A
46 mm	N/A	1217-31-046	N/A	N/A	N/A	N/A
48 mm	1217-01-048	1217-31-048	1217-11-048	1217-22-048	1217-32-048	1217-12-048
50 mm	1217-01-050	1217-31-050	1217-11-050	1217-22-050	1217-32-050	1217-12-050
52 mm	1217-01-052	1217-31-052	1217-11-052	1217-22-052	1217-32-052	1217-12-052
54 mm	1217-01-054	1217-31-054	1217-11-054	1217-22-054	1217-32-054	1217-12-054
56 mm	1217-01-056	1217-31-056	1217-11-056	1217-22-056	1217-32-056	1217-12-056
58 mm	1217-01-058	1217-31-058	1217-11-058	1217-22-058	1217-32-058	1217-12-058
60 mm	1217-01-060	1217-31-060	1217-11-060	1217-22-060	1217-32-060	1217-12-060
62 mm	1217-01-062	1217-31-062	1217-11-062	1217-22-062	1217-32-062	1217-12-062
64 mm	1217-01-064	1217-31-064	1217-11-064	1217-22-064	1217-32-064	1217-12-064
66 mm	1217-01-066	1217-31-066	1217-11-066	1217-22-066	1217-32-066	1217-12-066



Size	300 Series POROCOAT Coating	Multi-Hole POROCOAT Coating	Multi-Hole GRIPTION Coating
48 mm	1217-03-048	1217-20-048	1217-30-048
50 mm	1217-03-050	1217-20-050	1217-30-050
52 mm	1217-03-052	1217-20-052	1217-30-052
54 mm	1217-03-054	1217-20-054	1217-30-054
56 mm	1217-03-056	1217-20-056	1217-30-056
58 mm	1217-03-058	1217-20-058	1217-30-058
60 mm	1217-03-060	1217-20-060	1217-30-060
62 mm	1217-03-062	1217-20-062	1217-30-062
64 mm	1217-03-064	1217-20-064	1217-30-064
66 mm	1217-03-066	1217-20-066	1217-30-066
68 mm	N/A	1217-20-068	1217-30-068
70 mm	N/A	1217-20-070	1217-30-070
72 mm	N/A	1217-20-072	1217-30-072


Size	Bantam POROCOAT Coating	Bantam GRIPTION Coating
38mm	1217-20-038	1217-30-038
40mm	1217-20-040	1217-30-040
42mm	1217-20-042	1217-30-042
44 mm	1217-20-044	1217-30-044
46 mm	1217-20-046	1217-30-046

Table B-2: Actis™ Hip System Product Codes

Standard Offset	Description	Size
101011010	ACTIS COLLARED STD	SIZE 1
101011020	ACTIS COLLARED STD	SIZE 2
101011030	ACTIS COLLARED STD	SIZE 3
101011040	ACTIS COLLARED STD	SIZE 4
101011050	ACTIS COLLARED STD	SIZE 5
101011060	ACTIS COLLARED STD	SIZE 6
101011070	ACTIS COLLARED STD	SIZE 7
101011080	ACTIS COLLARED STD	SIZE 8
101011090	ACTIS COLLARED STD	SIZE 9
101011100	ACTIS COLLARED STD	SIZE 10
101011110	ACTIS COLLARED STD	SIZE 11
101011120	ACTIS COLLARED STD	SIZE 12

High Offset	Description	Size
101012010	ACTIS COLLARED HIGH	SIZE 1
101012020	ACTIS COLLARED HIGH	SIZE 2
101012030	ACTIS COLLARED HIGH	SIZE 3
101012040	ACTIS COLLARED HIGH	SIZE 4
101012050	ACTIS COLLARED HIGH	SIZE 5
101012060	ACTIS COLLARED HIGH	SIZE 6
101012070	ACTIS COLLARED HIGH	SIZE 7
101012080	ACTIS COLLARED HIGH	SIZE 8
101012090	ACTIS COLLARED HIGH	SIZE 9
101012100	ACTIS COLLARED HIGH	SIZE 10
101012110	ACTIS COLLARED HIGH	SIZE 11
101012120	ACTIS COLLARED HIGH	SIZE 12

Table B-3: Corail Hip System Product Codes

Standard Collarless (KS)	
Cat. No.	**Size**
L20106	6'
3L92507	8
3L92509	9
3L92510	10
3L92511	11
3L92512	12
3L92513	13
3L92514	14
3L92515	15
3L92516	16
3L92518	18

Standard Collared (KA)	
Cat. No.	**Size**
3L92498	8
3L92499	9
3L92500	10
3L92501	11
3L92502	12
3L92503	13
3L92504	14
3L92505	15
3L92506	16
3L92508	18
3L92521	20

High Offset Collarless (KHO)	
Cat. No.	**Size**
L20309	9
L20310	10
L20311	11
L20312	12
L20313	13
L20314	14
L20315	15
L20316	16
L20318	18
L20320	20

Coxa Vara Collared (KLA)	
Cat. No.	**Size**
3L93709	9
3L93710	10
3L93711	11
3L93712	12
3L93713	13
3L93714	14
3L93715	15
3L93716	16
3L93718	18

Table B-4: KINCISE Surgical Automated System Product Codes

Part No.	KINCISE Surgical Automated System
1000-00-101	KINCISE™ Automated Surgical Impactor
1002-00-102	KINCISE™ Battery Pack
1003-00-101	KINCISE™ 4-Port Battery Charger

Part No.	KINCISE Adapters
1010-01-102	KINCISE™ Anterior Broach Adapter
1011-01-101	KINCISE™ PINNACLE® Shell/Liner Impactor
1012-01-101	KINCISE™ PINNACLE® Shell/Liner Impactor
1013-00-101	KINCISE™ Bullet Tip Stem Inserter

EXHIBIT C – REFERENCES

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