DePuy Synthes
CLINICAL RESEARCH

PROTOCOL/CLINICAL INVESTIGATION PLAN (CIP)

Comparison of Alignment achieved using the VELYS™ Robotic-Assisted Solution versus Manual Instrumentation in Total Knee Arthroplasty: A Prospective, Non-Randomized Multi-Center post-market Clinical Investigation

Clinical Investigation Plan (CIP) Number:	DSJ_2019_08
Country:	USA
CIP Prepared By:	[redacted]
CIP Version & Date:	Rev F 06-June-2022
Clinical Investigation Sponsor:	DePuy Orthopaedics, Inc. [redacted]

PROTOCOL SIGNATURE PAGE

DSJ_2019_08: Comparison of Alignment achieved using the VELYS Robotic-Assisted Solution versus Manual Instrumentation in Total Knee Arthroplasty: A Prospective, Non-Randomized Multi-Center post-market Clinical Investigation		
Version	**Version Date**	**Description of changes**
C	22 July 2020	First version reviewed by Investigators
D	04-Feb-21	Updated to reflect regulatory clearance of the VELYS Robotic-Assisted Solution. Information on pre-clinical testing added, Exhibits C & D added with product codes.
E	11-Aug-21	Updated Primary objective to assessment of accuracy of alignment to plan as opposed to neutral.
F	06-June-22	Update to rules related to enrollment target reallocation. Removal of duplicate codes in Appendix D

Principal Investigator: I have read this protocol and agree to conduct this clinical investigation in accordance with the design and specific provisions outlined herein. I understand the protocol, and

I understand I am solely responsible to ensure the investigation is conducted accordance with Good Clinical Practices (GCP), applicable country regulations, the Declaration of Helsinki, applicable local regulations, the signed clinical study contract with Sponsor and with the protocol outlined herein.

I will conduct this study as outlined therein and will make reasonable effort to complete the study within the time period designated by the Sponsor.

I will provide copies of the protocol and all pertinent information to all individuals responsible to me who will assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed regarding the device and the conduct of the study.

I will fulfill the requirements of my Institutional Review Board (IRB)/ Ethics Committee (EC), or other oversight committee, to ensure complete and continual oversight of this clinical investigation.

I will use an Informed Consent Document approved by the Sponsor and my reviewing IRB/EC (where required).

I agree to report all information or data in accordance with the protocol and, in particular, I agree to report any serious adverse events, device related adverse events, or procedure related adverse events as defined in this protocol to the Sponsor and comply with all adverse events reporting requirements of my reviewing IRB/EC.

I agree to permit the Sponsor, its authorized representatives, my reviewing IRB/EC, and any regulatory authority/body access to all records relating to the clinical investigation. The below signature confirms I have read and understood this protocol and its associated amendments or attachments and will accept respective revisions or amendments provided by the Sponsor.

PRINTED OR TYPED NAME	SIGNATURE	DATE
Principal Investigator		

Table of Contents

1 SUMMARY

Title:	Comparison of Alignment achieved using the VELYS Robotic-Assisted Solution versus Manual Instrumentation in Total Knee Arthroplasty: A Prospective, Non-Randomized Multi-Center post-market Clinical Investigation
Short Title:	Clinical Evaluation of the Accuracy of the VELYS Robotic-Assisted Solution
Protocol Number:	DSJ_2019_08
Treatment Devices:	The treatment device is the VELYS Robotic-Assisted Solution which is used for assessing the anatomy of a patient's knee, assisting in the planning of the position of the femur and tibia implant components intra operatively and assisting the surgeon with the bone preparation during total knee arthroplasty. The system will be utilized to implant ATTUNE total knee replacements. Any of the commercially available configurations of the ATTUNE primary knee system are permitted for use according to the standard of care at the site. Those subjects treated using VELYS Robotic-Assisted Solution will be referred to as the Robotics cohort.
Control Device:	The control devices are the ATTUNE Intuition instruments which are manual instruments. This instrument system will be utilized to implant ATTUNE total knee replacements. Any of the commercially available configurations of the ATTUNE primary knee system are permitted for use according to the standard of care at the site. Those subjects treated using the Intuition Instruments will be referred to as the Manual cohort.
Intended Use for the Device:	The intended use of the VELYS Robotic-Assisted Solution is to assist the surgeon to perform primary total knee arthroplasty utilizing the ATTUNE knee system.
Primary Objective:	To determine whether the accuracy to plan of the long leg alignment achieved with the VELYS Robotic-Assisted Solution is non-inferior to the accuracy to plan of the long leg alignment achieved with the manual ATTUNE Intuition instrumentation. This will be assessed on long-leg X-rays taken at 12 weeks. • Note: If non-inferiority is successfully demonstrated, then the study will be deemed to be successful, and a test for superiority of accuracy to plan of the long leg alignment achieved with VELYS Robotic-Assisted Solution will be conducted.
Secondary Objectives:	Evaluate the nature, severity, and frequency of local adverse events associated with the use of the VELYS Robotic-Assisted Solution in total knee arthroplasty during the procedure and within the subsequent 12 weeks, 90 days[1] and 1 year. Conduct intra-operative clinical assessment of soft tissue damage in both Manual and Robotics cohorts. Summarize the alignment outliers (>3 degrees outside of plan) in both Manual and Robotics cohorts. Summarize surgical time for the Robotics and Manual cohorts. Summarize individual component alignment achieved with manual instruments and Robotics in the frontal and sagittal planes, specifically: distal femoral varus-valgus (FM), proximal tibial varus-valgus (TM), femoral component flexion and tibial slope.

[1] This is a specific analysis of data to determine number of AEs that occurred within 90 days of the procedure determined at 1year follow up – there is no 90 day visit.

Title:	Comparison of Alignment achieved using the VELYS Robotic-Assisted Solution versus Manual Instrumentation in Total Knee Arthroplasty: A Prospective, Non-Randomized Multi-Center post-market Clinical Investigation
Short Title:	Clinical Evaluation of the Accuracy of the VELYS Robotic-Assisted Solution
Protocol Number:	DSJ_2019_08
Tertiary Objectives:	To evaluate impact of surgeon learning curve on the VELYS Robotic-Assisted Solution on accuracy of surgical procedure (assessed via accuracy of long leg alignment to plan), patient reported outcomes, safety, and surgical time. Comparison of patient reported outcomes (EQ-5D 5L, Knee Injury and Osteoarthritis Outcome Score (KOOS), Forgotten Joint Score (FJS), Pain and Satisfaction) for the Robotics cohort vs. the Manual cohort at 12 weeks and 1 year post-operatively. Comparison of length of hospitalization/stay for the Robotics cohort vs. the Manual cohort. For the Robotics cohort there will be additional exploratory objectives to measure the correlation between the various parameters that the system records in the case report and what is measured via other methods post operatively.
Study Design:	Prospective sequential controlled cohort study. Each site will enroll Subjects into the Manual cohort until their enrollment target has been reached, and then will enroll Subjects into the Robotics cohort. Level of evidence: Level II
Number of Sites:	Up to 8 sites in the USA. Cohort reallocation is permitted.
Study Subject Population	Patients aged 22-85 years who meet the indications of the ATTUNE Knee system in a primary case including patients with severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.
Sample Size	N= 200 will be enrolled; 100 in the manual surgical technique arm, and 100 in the robotic arm.
Study Duration:	It is anticipated that recruitment for both arms will be completed in 6 months. Follow-up is 1 year, therefore, the total planned study duration is approximately 18 months.
Procedure Schedule	Subjects included in the investigation will be evaluated pre-operatively, at 12 weeks and 1 year postoperatively. **See Time & Events Table for details.**
Safety	Type and frequency of Adverse Events will be collected. Site Ethics Committees/IRBs will provide oversight for study Subject safety.

Table 1-1: Time and Events Table

	Pre-op	Operative	12wks	1yr
Required	-90 to 0d	Day 0	7d to 182d	**183d** to 547d
Preferred	-90d to 0d		28d to 112d	335d to 395d
Informed Consent	S			
eCRF: Study Visit	E		E	E
eCRF: Demographics	E			
eCRF: Medical History	E			
eCRF: Height & Weight	E			
eCRF: Range of Motion	E		E	
eCRF: KOOS	P		P	P
eCRF: FJS			P	P
eCRF: EQ-5D-5L	P		P	P
eCRF: Subject Knee Outcome (Pain & Satisfaction)	P		P	P
eCRF: Pain Catastrophizing Scale	P			
eCRF XR: Radiographs				
Long leg AP (weight bearing)	X[2]		X	
Lateral view	X[2]		X	
eCRF: Study Procedure		E		
eCRF: Device Log		E		
eCRF: Adverse Event		E*	E*	E*
eCRF: Device Deficiency		E*		
eCRF: Discharge		E		
System Case Report (Robotics cohort only)		D		
eCRF: Subject Completion/Discontinuation	E*		E*	E*
eCRF: Protocol Deviation	E*		E*	E*
eCRF: Reoperation			E*	E*

LEGEND:
S = Remains on site as source document
E = Source data transcribed onto electronic Case Report Form (eCRF) and submitted to sponsor
E* = Source data transcribed onto eCRF and submitted to sponsor, as needed
P = Patient Recorded Outcome, completed by Subject, data entered on eCRF & submitted to sponsor
X = X-ray image to be submitted to core imaging lab for analysis
D = case reports stored on the VELYS Robotic-Assisted Solution are the source document with copies of all reports related to Subjects sent to sponsor at the end of the study.

[2] Pre-operative assessment window is -90d to 0d, but pre-operative radiographs may be taken from -180d (or older, if they are still determined to be acceptable for surgical planning at the discretion of the PI) to day of surgery to avoid increased radiation exposure if the required views have already been taken as standard of care prior to -90d.

2 INTRODUCTION

Primary total knee arthroplasty (TKA) is a common, elective surgical procedure performed frequently to alleviate pain most commonly due to osteoarthritis, with factors such as age (older being more frequently replaced) and gender (females being more frequent sufferers of knee OA) influencing the patient demographics. The clinical demand for TKA use is increasing, with demand for primary total knee replacement in the United States alone being forecast to rise by over 600% to 3.48M from 2005 to 2030[1].

The surgical process is a key contributor to the success of TKA with orthopaedic surgeons striving to execute bone resections and make soft tissue adjustments to achieve optimal implant position; ensuring longevity and improved patient function and satisfaction. Therefore, over time there has been a continual evolution in the techniques and technologies employed to achieve this goal. Manual instrumentation including jigs, fixtures and cutting guides are used to guide the surgeons' resections relative to anatomical landmarks such as the tibial axis, femoral canal and posterior condylar axis. This method was first developed in the 1980s and when combined with surgeon skill and experience generally results in good outcomes and remains the most commonly used methodology for implanting a total knee. However, up to 6% of patients who undergo a primary TKA may require a revision within 5 years of the procedure[2] and whilst the majority of revisions are attributed to infection it is widely accepted that implant positioning influences the rate of other leading causes of revision such as instability and loosening [3].

One of the key parameters in the outcome of the surgical procedure is the alignment of the knee implant components relative to the mechanical axis of the leg. The mechanical alignment philosophy was proposed by Insall and has become the standard procedure employed [4]. Mechanical axis alignment is defined as the line drawn from the center of the femoral head through the center of the knee and ankle. The knee is generally considered to be in proper alignment when these three points are collinear in the frontal plane [4-6]. Many authors have observed that the correct alignment of the lower limb is correlated with clinical success in total knee arthroplasty [6-8].

In a bid to increase consistency in the achievement of parameters such as alignment, Computer Assisted Surgery (CAS) was developed in the early 2000's. Optical localization technology is used to collect intra-operative data and track relative position of the bones and instruments during surgery. Intra-operative data is used to register the patient anatomy and enables the surgeon to define and adjust planning for the placement of the implant. Based on the plan, the system guides the surgeon to position cutting blocks which in turn controls alignment of the cutting plane for the required steps. More recently robotic systems have been introduced which build on the same technology developed for CAS whilst providing more control or assistance to the surgeon during execution of the resections to increase the probability of achieving the desired outputs. The VELYS Robotic-Assisted Solution is currently being developed by the sponsor and is the focus of this study.

2.1 Summary of Preclinical/Clinical Experience

Bench testing was performed on the subject device, VELYS Robotic-Assisted Solution, in accordance with the product risk analysis and product requirements. This included testing that addressed accuracy and repeatability, service life, mechanical integrity and usability of the system. All acceptance criteria were met, and no issues of Safety or Effectiveness were identified.

A cadaveric study compared the accuracy of the VELYS Robotic-Assisted Solution to manual instrumentation. Five surgeons each performed eight bilateral total knee replacement surgeries – with the VELYS Robotic-Assisted Solution one side and conventional instruments (ATTUNE Intuition) on the contralateral side (total sample size of 40). Bone resection depth levels were measured intra-operatively using digital calipers. Resected bones were CT and laser scanned, then bone preparation was completed, followed by implanting. Final implant position was measured using additional laser scanning.

During each case, surgeons evaluated the integrity of defined knee soft tissue structures (medial collateral ligament [MCL], lateral collateral ligament [LCL], posterior cruciate ligament [PCL], Posterior Medial capsule, Posterior Lateral capsule, and the patellar ligament) after completing all bone resections. Additionally, surgeons were asked to evaluate resected bone quality, overall final long leg alignment, and soft-tissue balance during trialing.

The robotic-assisted surgical cohort had statistically smaller mean absolute errors for femoral varus-valgus angle ($p<0.000$), tibial varus-valgus angle ($p=0.001$), and tibial proximal resection thickness ($p<0.000$) and were statistically equivalent to manual instrumentation for femoral flexion-extension angle, femoral internal external angle, femoral distal resection depth and tibial flexion-extension (posterior slope) angle. The robotic-assisted cohort was also found to have statistically smaller errors in final implant alignment for femoral varus-valgus angle, femoral flexion-extension and tibial varus-valgus angles.

All inspected soft tissue was uncompromised following robotic-assisted bone resection. After each procedure, all surgeon participants responded 'Yes' when asked if the final long leg alignment was clinically acceptable. In addition, all surgeon participants responded 'Yes' when asked if the knee soft tissue was stable and balanced.

2.2 Summary of Published Literature

There are currently no published clinical results for the VELYS Robotic-Assisted Solution, however, the use of robotic systems in orthopaedics has been steadily increasing in popularity over the past 10 years. Literature suggests that the currently available systems can increase the accuracy vs. manual instrumentation in both unicondylar knee arthroplasty (UKA) [9-11] and TKA [12-15].

A learning curve has been identified with the introduction of robotic systems for UKA and TKA which is associated with an increase in the operating time but importantly, based on the current literature this period is not associated with an increase in adverse events or a reduction in accuracy [16-21]. There is no consensus on the length of the learning curve with large variation in the number of cases found in these studies. It will clearly vary depending on the system, the amount of previous experience with CAS/Robotically assisted surgery, the training and support provided to the new user and how steady state is defined.

Translation of the improvement in accuracy to improvements in other outcomes such as patient satisfaction, pain and function are less clear with some studies finding no difference [22, 23] and other studies finding subtle improvements [24-26]. This may be due to these clinical outcomes being highly dependent of factors beyond the accuracy of the placement of the implant.

3 RATIONALE

3.1 Study Rationale

VELYS Robotic-Assisted Solution is a new system without pre-existing clinical data. Adoption of VELYS Robotic-Assisted Solution will be dependent on demonstrating that the system can effectively aid the surgeon to achieve the targeted alignment when compared to manual instrumentation. Furthermore, this study will provide opportunities for active post-market clinical follow-up including documentation and review of adverse effects in relation to use of the study device.

3.2 Study Design Rationale

The study is designed as a multi-center prospective sequential controlled cohort study. Each site will enroll Subjects into the manual cohort until their enrollment target has been reached, and then will enroll Subjects into the robotic cohort. The manual cohort will be used as benchmark data that the robotic cohort can be compared to. A sequential design was chosen to mitigate the risk of learnings from the study arm influencing the control arm. As the primary objective is accuracy which can be measured objectively randomizing was deemed to not add any benefit. Likewise blinding the Subjects would add significant complexity to the study without influencing the objective measures that are the focus of the study. A single knee system (ATTUNE) will be used to minimize variation.

3.3 Rationale of Endpoints

The primary endpoint of long leg alignment accuracy measured at 12 weeks was selected as accuracy of implant placement is the element of the procedure that the robotic system has greatest influence over. The mechanical alignment philosophy was proposed by Insall and has become the standard procedure employed [4]. The theory being that the knee replacement should be loaded evenly on the medial and lateral condyles to avoid subsidence or loosening at the side under greater load. This was subsequently supported by studies that showed improved survivorship of knees implanted in mechanical alignment Vs. those implanted with a varus or valgus alignment [6, 8]. More recently some authors have challenged the criticality of implanting the knee in perfect neutral alignment with some variation accepted with the goal of better replication of the patients' specific knee alignment and improved management of the soft tissues of the knee [27-29]. Either way, achieving the planned long leg alignment is deemed important in the survivorship and function of the knee replacement and can be used as a surrogate measure of the procedure success and therefore the VELYS Robotic-Assisted Solution's success in guiding the surgeon to this goal.

The long leg alignment can be measured via X-ray at the first follow up (typically 6-12 weeks) when the Subjects are full weight bearing and the swelling has subsided sufficiently to allow the patient to reach full extension. Assuming good implant fixation, which has been demonstrated for the ATTUNE system via radiostereometric analysis [30] the alignment is unlikely to change significantly at later time points therefore the 12 week time point is considered an appropriate time to measure the primary endpoint. It is also the best opportunity to measure the direct output of the surgical process without the influence of anatomical adaptation/changes over time. The secondary and tertiary endpoints of this study pertain to other measurements of component alignment, safety outcomes, surgical time, patient outcomes, and health economics measures that are of interest to the Sponsor.

3.4 Rationale of Study Population

Patients aged 22-85 years who meet the indications of the ATTUNE Knee system in a primary case including patients with severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis or rheumatoid arthritis are targeted for this study. The study is limited to primary TKA and excludes failed previous TKA as the VELYS Robotic-Assisted Solution is only cleared for use in primary TKA. In addition to contraindications specified by the TKA implant system used by the surgeon, contraindications for using the VELYS Robotic-Assisted Solution are as follows:

- Patients for whom a hip center of rotation cannot be established using the VELYS™ Robotic-Assisted registration protocols.
- Patients in whom the necessary bony landmarks needed for registration are not present or accessible.

These contraindications for the VELYS system are not included in the exclusion criteria for the study as they may be challenging to identify pre-operatively and may only become evident when the surgeon has made an intra-operative assessment. Information on the management of subjects in whom these contra-indications are detected intra-operatively is given in Table 7-3.

4 SUBJECT DEFINITION

Patients aged 22-85 years who meet the indications of the ATTUNE Knee system in a primary case including patients with severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis or rheumatoid arthritis may be considered for enrollment in this study.

Subjects who do not meet all inclusion criteria or who meet any of the exclusion criteria are withdrawn from the study

4.1 Inclusion Criteria

Subjects meeting all of the following specific criteria will be considered for participation in the study:

a) Subject is male or female and between the ages of 22 and 85 years at the time of consent, inclusive.

b) Subject has a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis or rheumatoid arthritis and in the opinion of the Investigator, is a suitable candidate for primary TKA using the devices described in this CIP with either resurfaced or non-resurfaced patellae.

c) Subject that is willing to give voluntary, written informed consent to participate in this clinical investigation and authorize the transfer of his/her information to the Sponsor

d) Subject is currently not permanently bedridden, as determined by the Investigator

e) Subject, in the opinion of the Investigator, is able to understand this clinical investigation and is willing and able to perform all study procedures and follow-up visits and co-operate with investigational procedures.

f) Subject is able to read and comprehend the Informed Consent Document as well as complete the required PROs in English.

g) Subject's pre-operative alignment is such that (in the opinion of the Investigator) it is appropriate for

it to be adjusted to mechanical long leg alignment during surgery.

4.2 Exclusion Criteria

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

a) The Subject is a woman who is pregnant or lactating.

b) Contralateral knee has already been enrolled in this study.

c) Subject had a contralateral amputation.

d) Previous partial knee replacement (unicompartmental, bicompartamental or patellofemoral joint replacement), patellectomy, high tibial osteotomy or primary TKA in affected knee.

e) Subject has an active local or systemic infection

f) Subject has loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable in the opinion of the Investigator (e.g. absence of musculo-ligamentous supporting structures, joint neuropathy)

g) Subject has severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.

h) Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three (3) months.

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

4.3 Definition of Subject Enrollment

A patient will be considered enrolled when they have provided written informed consent to participate in this Investigation, as well as Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization within the informed consent or a separate document as required per site policy.

5 OBJECTIVES

5.1 Primary Objective

The primary objective of this clinical investigation is to evaluate whether the accuracy to plan of the long leg alignment achieved with VELYS Robotic-Assisted Solution is non-inferior to the accuracy to plan of the long leg alignment achieved with the manual ATTUNE Intuition instrumentation. This will be assessed by measuring the Hip-Knee-Ankle angle (HKA) on long-leg X-rays taken at 12 weeks and comparing to the planned HKA.

This will be followed by a subsequent superiority analysis to determine if the VELYS Robotic-Assisted Solution is more accurate in achieving this goal than the manual ATTUNE Intuition Instrumentation.

5.2 Secondary Objectives

- Evaluate the nature, severity, and frequency of local adverse events associated with the use of the Robotic system in total knee arthroplasty during the procedure and within the follow up period, assessed at 12 weeks, 90 days (specific cut of the data only, no visit) and 1 year.
- Intra-operative clinical assessment of soft tissue damage in both Manual and Robotics cohorts. The condition and function of the key knee structures (medial collateral ligament (MCL), lateral collateral ligament (LCL), posterior cruciate ligament (PCL), patella tendon (PT), posterior lateral capsule (PLC) and posterior medial capsule (PMC) will be assessed intra-operatively.
- Summarize the alignment outliers (long leg alignment >3 degrees outside of plan) in both Manual and Robotics cohorts.
- Summarize surgical time for the Robotics and Manual cohorts; including skin-to-skin time, operating room utilization (wheels in-to-wheels out) and total operating room time (including set up and clean down).
- Summarize individual component alignment achieved with manual instruments and Robotics in the frontal and sagittal planes, specifically: distal femoral varus-valgus (FM), proximal tibial varus-valgus (TM), femoral component flexion and tibial slope.

5.3 Tertiary Objectives

Additional tertiary objectives are:

- To evaluate impact of surgeon learning curve on the Robotic system on accuracy of surgical procedure (assessed via accuracy to plan of long leg alignment), patient reported outcomes, safety, and surgical time.
- Summarize the patient reported outcomes (EQ5-D, KOOS, FJS, Patient Knee Pain and Satisfaction) for the Robotics cohort vs. the Manual cohort.
- Summarize the length of hospitalization/stay for the Robotics cohort vs. the Manual cohort.

For the Robotics cohort there will be the following additional exploratory objectives:

- Assessment of the correlation between the planned long leg alignment and the post-resection long leg alignment recorded on the VELYS Robotic-Assisted Solution case report.
- Assessment of the correlation between the post-resection long leg alignment recorded on the VELYS Robotic-Assisted Solution case report and the long leg alignment measured via weight bearing X-ray at 12 weeks.
- Assessment of the correlation between the planned medial and lateral gaps in extension and the post-resection medial and lateral gaps in extension recorded on the VELYS Robotic-Assisted Solution case report.
- Assessment of the correlation between the planned medial and lateral gaps in flexion and the post-resection medial and lateral gaps in flexion recorded on the VELYS Robotic-Assisted Solution case report.
- Assessment of the correlation between the post-resection medial and lateral gaps in flexion and extension and the thickness of the tibial insert implanted as recorded in the device log.

- Assessment of the reliability of the VELYS Robotic-Assisted Solution via review of information captured within device deficiency forms.

The primary, secondary and tertiary clinical endpoints and the relevant statistical analyses are described in detail in Section **8.8.**

Table 5-1: Summary of Primary and Secondary Objectives with Respective Endpoints

	Outcome	Endpoint Timing
Primary Endpoint	Accuracy to plan of Long leg alignment assessed by measuring the HKA on a long leg X-ray.	12 weeks
Secondary Endpoints	Evaluate the nature, severity, and frequency of local adverse events associated with the use of the Robotic system in total knee arthroplasty during the procedure and within the subsequent 12 weeks, 90 days and 1 year.	12 weeks, 90 days (Specific cut of data to determine number of AEs within 90 days determined at 1year follow up) 1 year
	Intra-operative clinical assessment of soft tissue damage in both Manual and Robotics cohorts.	Operative
	Summarize the alignment outliers (>3 degrees outside of plan) in both Manual and Robotics cohorts.	12 weeks
	Summarize surgical time for the Robotics and Manual cohorts; including skin-to-skin time, operating room utilization (wheels in-to-wheels out) and total operating room time (including set up and clean down).	Operative
	Summarize individual component alignment achieved with manual instruments and Robotics in the frontal and sagittal planes, specifically: distal femoral varus-valgus (FM), proximal tibial varus-valgus (TM), femoral component flexion and tibial slope	12 weeks
Tertiary Endpoints	To evaluate impact of surgeon learning curve on the Robotic system on accuracy of surgical procedure (assessed via accuracy to plan of long leg alignment), patient reported outcomes, safety, and surgical time.	Operative 12 weeks 1 year
	For both cohorts evaluate change from baseline for EQ-5D-5L score	12 weeks 1 year
	For both cohorts evaluate change from baseline for KOOS	12 weeks 1 year

	Outcome	Endpoint Timing
	For both cohorts evaluate FJS	12 weeks 1 year
	For both cohorts evaluate change from baseline for Satisfaction	12 weeks 1 year
	For both cohorts evaluate change from baseline for Pain	12 weeks 1 year
	For both cohorts evaluate length of hospitalization stay post op	Discharge
	For Robotic cohort assessment of correlation between the planned long leg alignment and the post-operative long leg alignment recorded on the VELYS Robotic-Assisted Solution case report	Operative
	For Robotic cohort assessment of the correlation between the post-operative long leg alignment recorded on the VELYS Robotic-Assisted Solution case report and the long leg alignment measured via weight bearing X-ray at 12 weeks.	12 weeks
	For the Robotic cohort assessment of the correlation between the planned medial and lateral gaps in extension and the post-resection medial and lateral gaps in extension recorded on the VELYS Robotic-Assisted Solution case report.	Operative
	For the Robotic cohort assessment of the correlation between the planned medial and lateral gaps in flexion and the post-resection medial and lateral gaps in flexion recorded on the VELYS Robotic-Assisted Solution case report.	Operative
	For the Robotic cohort assessment of the correlation between the post-resection medial and lateral gaps in flexion and extension and the thickness of the tibial insert implanted as recorded in the device log.	Operative
	For the Robotic cohort assessment of the reliability of VELYS Robotic-Assisted Solution based on the number and type of device deficiencies that occur	Operative

6 STUDY DESIGN

This study is designed as a prospective sequential controlled cohort study. Each site will enroll Subjects into the Manual cohort until their enrollment target has been reached, and then will enroll Subjects into the Robotic cohort. Level of Evidence is II.

There will be a maximum of 8 sites that will recruit a total of 200 Subjects (100 manual control arm and 100 in the Robotic study arm). Each site will use the implant configuration(s) that fit with their standard

of care. Both resurfaced patella and non-resurfaced patella are permitted in this investigation, consistent with the site's standard of care.

Each site is expected to implant approximately 10-20 knees in the control arm and 10-20 knees in the study arm. Details regarding sample size are presented in Section 8.7 Sample Size Justification. Single stage bilateral procedures are not permitted in the study, for staged bilateral procedures only one knee per patient can be enrolled in the study.

The Sponsor will monitor overall project enrollment. The Sponsor can authorize a shift of a group of Subjects from one site to another to maintain project timelines. For example, the Sponsor can reduce the cohort of a slow-enrolling site to a faster-enrolling site and the faster-enrolling site will assume responsibility for the reallocated cohort. To prevent learnings from the Robotic procedures influencing the execution of the surgery in the manual control arm, once the study arm has been initiated at a site it will only be permissible to add additional enrolment in the study arm and not the control arm.

7 PROTOCOL

7.1 Subject Enrollment

No study-related procedure, eCRF or form associated with this study can be completed until written Informed Consent is obtained for that Subject (see Section 4.3. Definition of Subject Enrollment) except for information that was gathered previously as part of the standard of care at the site.

7.1.1 Subject Screening

All patients who are candidates for primary TKA, and who generally meet the study requirements, will be screened for general eligibility by reviewing the surgical schedule. Those patients who are approached for the study will be listed on the Consenting Log in order to document that the Subject selection was unbiased. The consenting log will document the date the patient was approached for the study and whether they consented.

After signing the Informed Consent, study Subjects are defined as "enrolled" and site will then complete the non-standard of care pre-operative data collection.

It is expected that complete data collection will be obtained for all enrolled Subjects, with the only exception being a Subject who is subsequently withdrawn. See section 7.3 Discontinuation of Subject Participation for details. For Pre-operative Subject withdrawals the following are the minimum eCRFs to be completed: inclusion/ exclusion criteria, Demographics, Medical History (targeted) and surgical history.

7.1.2 Subject 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 21 CFR Part 50, the Declaration of Helsinki, and this study protocol.

All Informed Consent Documents (ICD) must have favorable opinion of the responsible IRB/EC (Section 12.1). Consent of a Subject needs to be from the subject themselves and documented on an ICD and the process documented within source documentation.

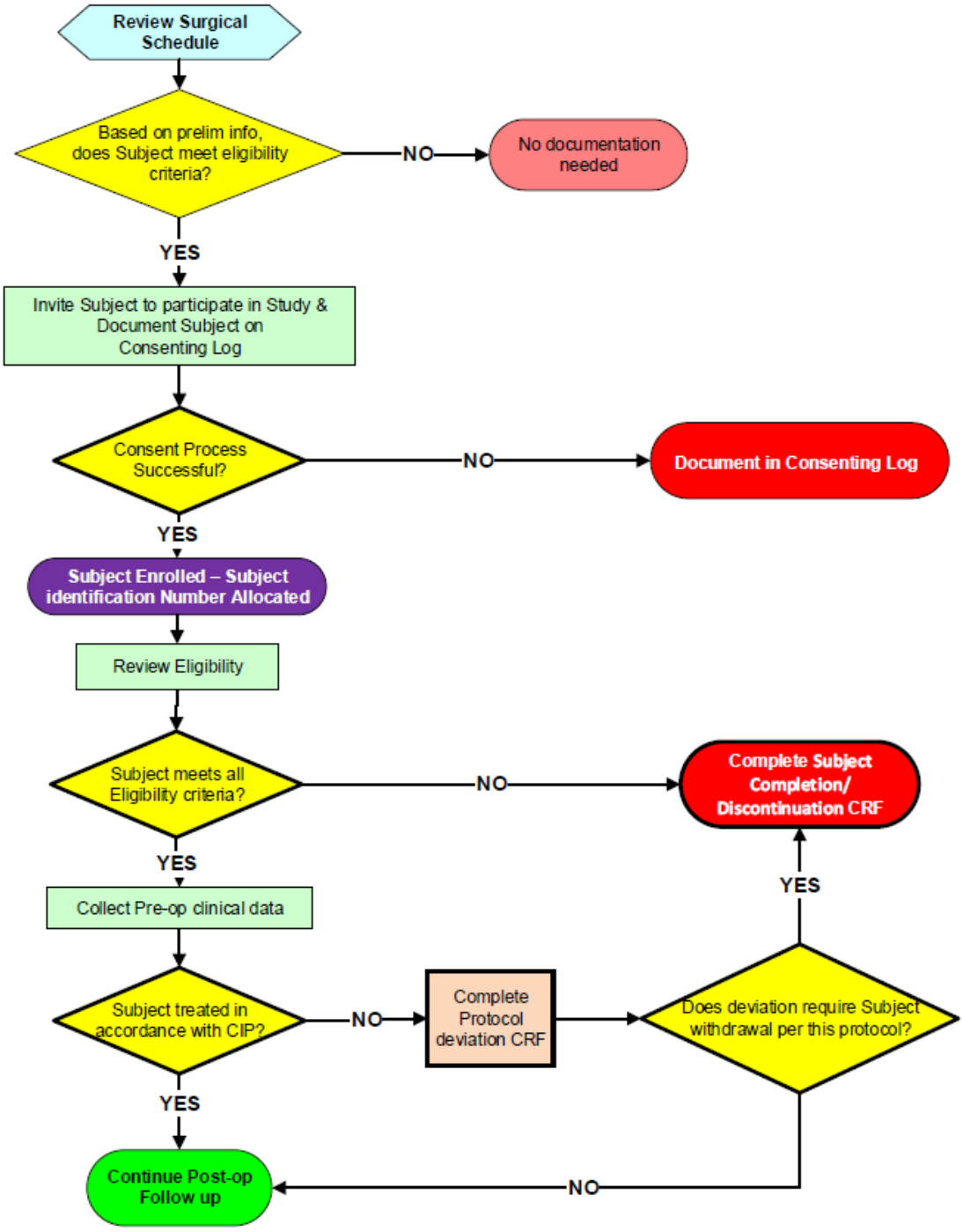
Screening, consenting and enrollment are illustrated in Figure 7-1. The Investigator or trained designee preliminarily screens to determine if a patient generally meets the eligibility criteria for the study. If so, the Investigator or trained designee shall offer study participation to those patients. Having explained the study intent to the Subject, the Investigator or trained designee shall offer to answer any of the Subject's questions. If the Subject then agrees to participate, they must add their signature and write the date on the IRB/EC's approved ICD and this document must then be countersigned and dated by the person taking consent.

No names or dates should be prepopulated or completed by someone other than the person providing the signature.

Upon successful completion of the consent process, the Patient is enrolled and is identified as a Study Subject.

Acquiring Consent on Day of Surgery: If the ICD signatures are acquired on the day of surgery, the time of the signature must be documented on the ICD signature page to support that consent was obtained from the study Subject prior to any treatment-related and/or mood-altering medications being administered. The documentation of time is not required where consent is obtained on a day prior to surgery.

Figure 7-1: Screening and Enrollment Process



7.1.3 Subject Identification Numbering

The **database assigns Subject ID numbers** upon data entry into the database.

Each site is identified uniquely, e.g., 01-, 02- followed by 001 for the first Subject at the site, 002 for the second Subject and so on. Together the Site number and the Subject number will then become the unique identifier of the Subject and will be recorded on each page of the eCRF, and on the Consenting log.

In the instance of a Subject being enrolled, a number assigned and subsequently the Subject is deemed ineligible prior to undergoing the procedure, a Subject Completion/Discontinuation eCRF should be completed and the criteria not met should be documented on the inclusion/exclusion eCRF. In the case of pre-operative withdrawals, or subjects that are withdrawn intra-operatively due to the required equipment not being available a further Subject will be enrolled to replace the withdrawn Subject in order to ensure 200 Subjects have the procedure. Once a Subject identification number is assigned, it may not be reused. Refer to Section 7.3.1 Enrollment Replacement Rules.

7.2 Study Procedures

This section is applicable to enrolled study Subjects. This study does not limit the procedures involved in the treatment of the subject outside of the surgical process. The pre-operative, anesthesia, post-op care, and follow up are not research procedures, and therefore are not restricted by the study.

This section details the study requirements in terms of the pre-operative, operative, and post-operative management of Subjects. Visit evaluations include clinical and radiographic evaluations and Subject self-assessments. eCRFs must be submitted to the sponsor as outlined in Section 11.7 Case Report Form Completion and Data Submission.

The patient reported outcome instruments KOOS, EQ-5D-5L, FJS and Subject Knee Outcomes (Pain and Satisfaction scores) are compulsory at all sites.

7.2.1 Detailed Instructions on Data Collection

The following evaluation tools are to be used to collect and evaluate study subject outcomes pre-operatively, intra-operatively and post-operatively as outlined in Table 7-1 and in accordance with the Time and Events Table (Table 1-1). Patient reported outcomes (in italics) will be provided in hard copy printed sets for completion by the study subject during the in clinic visit- at Pre-op, 12 weeks and 1 year timepoints.

While in clinic visits are the preferred method for the 1 Year visit, if unforeseen issues arise causing the inability to conduct an in clinic visit, the site may review adverse events with the study subject via telephone or other SOC virtual means. These methods may only be used for the 1 year visit and may not be used to collect PRO data.

The details associated with administration of PROs are described in Section 7-2-2.

Table 7-1: Data collection, with Subject Completed forms in italics

Case Report Form	Details of Evaluation	Pre-Op/ Intra-op/Post—Op
Study Visit	Assists study site to verify that study visit occurred in the appropriate interval and by the appropriate means (at clinic or by phone)	Pre-op & Post-op
Demographics	Authorized medical personnel will collect basic demographics.	Pre-Op Only
Targeted Medical History	Authorized medical personnel will collect information about aspects of the patient's medical history that is pertinent to the TKA procedure.	Pre-Op Only
Vital Signs (Height and Weight)	Authorized medical personnel will collect patient's height and weight.	Pre-Op Only
Range of Motion	Authorized medical personnel will collect patient's Range of Motion pre op and at the 12 week visit	Pre-op & Post-op
Knee injury and Osteoarthritis Outcomes Score (KOOS)	A member of the research team will administer each of these PROs as detailed in Section 7-2-2, below. The total time for completion per study Subject is approximately 10-15 minutes.	Pre-op & Post-op
Forgotten Joint Score		Post-op Only
Pain Catastrophizing Scale		Pre-op Only
Subject Knee Outcomes (Pain & Satisfaction)		Pre-op & Post-op
EQ-5D-5L		Pre-op & Post-op

Case Report Form	Details of Evaluation	Pre-Op/ Intra-op/Post—Op
Radiographic Evaluation	Weight bearing long leg AP and Lateral radiographs will be obtained pre-operatively and post-operatively. Note: Pre-operative radiographs can be taken up to -180 days prior to the surgical event. Pre-operative Radiographs provide background information only, and do not constitute either a primary or secondary endpoint. Radiographic guidelines will be provided to sites in an Image Acquisition Protocol. Image assessment will be done by an Independent Radiographic Reviewer.	Pre-Op & Post-Op
Operative Detail	Description of Subject's surgical procedure including such items as configuration used, surgery time, resection time, surgical technique details, planned femoral and tibial resection angles, soft tissue assessment. For the Robotic cohort the system case ID will be recorded.	Intra-Op
Discharge	Information of when the patient is discharged and the location that the patient is discharged to.	Discharge
VELYS Robotic-Assisted Solution Case Report	Report generated by system including the pre resection long leg alignment and medial and lateral gaps, planned resection angles and the post-resection alignment.	Intra-Op (Robotic cohort only)
Device Log	Identification of devices implanted, including product codes, lot numbers and Universal ID code/device identifier.	Intra-Op
Adverse Event	Includes diagnosis, date of onset, date of awareness, treatment and classification of the AE.	As required (Intra-Op and/or Post-Op)

Case Report Form	Details of Evaluation	Pre-Op/ Intra-op/Post—Op
Device Deficiency	Any inadequacy in the identity, quality, durability, reliability, safety or performance of the VELYS Robotic-Assisted Solution, including malfunction, use errors or inadequacy in information supplied by the manufacturer will be recorded on the Device Deficiency form	As required Intra-Op for Robotics Cohort only
Subject Completion/ Discontinuation	Reason for follow-up being concluded (e.g., completed study requirements, consent withdrawn)	As required (Pre-op or Post-Op)
Protocol Deviation	Nature of deviation that has occurred and reason why	As required (Pre-op or Post-Op)

7.2.2 Subject Evaluation Tools

The Patient Reported Outcomes included in this study are listed in Table 7-2 above, along with the other data to be captured. The PRO assessments should be administered before any diagnostic work-up, study procedure or clinical measurement is performed on the visit day in clinic. If consent is the same day of surgery, consent should be taken and PROs completed before administering any mood altering medication.

Each of the questionnaires should be completed by the Subject, and usually takes 2-3 minutes per questionnaire to complete.

The PRO CRFs should be administered in the following order: EQ-5D-5L, KOOS, Subject Knee Outcomes then FJS. The PROs may never be administered verbally, the Subject personally completes their portions of each document.

Should a 1 year visit be conducted remotely as described in 7.2.1 the PROs may be mailed to the subject with a pre-paid return method included. The subject's signature and date of completion should be provided so that this signature can be verified against the consent form to ensure the subject was the individual completing the questionnaire.

7.2.3 Pre-operative Management

Prior to surgery, the data in Table 1-1 (the Time & Events Table) must be collected for each enrolled Subject. The interval for obtaining the Informed Consent and pre-op assessments is from -90 days through day 0 (day of surgery) as designated on the Time & Events Table (Table 1-1). The -90 day time frame is important to support PROs being collected closer to the time of surgery since it is anticipated that there may be deterioration in function as the patient awaits surgery. The interval for obtaining preoperative radiographs is extended to -180 days to day 0 (day of surgery) so that study subjects would not need to have repeat radiographs if any radiographs that had been taken as standard of care prior to the Subject being enrolled were the required views. This will be allowed to minimize the study subject's unnecessary exposure to radiation. Note, it would be preferred if the radiographs were taken from -90 days through day 0, however if radiographs are available that exceed the 180 day maximum timepoint, they can still be used if they are thought to be acceptable for preoperative surgical planning (as per their standard of care) at the discretion of the PI.

Once written informed consent is given, the below will be followed:

- Pre-operative Radiograph assessment (unless acquired prior to enrollment), Subject History and all Patient Reported Outcome questionnaires will be completed.
- The TKA surgical details and any procedure or device related intra-operative complications are captured on eCRFs for subsequent analysis.
- Follow-up intervals include 12 week and 1 year post-operative clinic visits. Post-operative radiographs will be taken at the 12 week follow-up.

7.2.4 Operative Management

The surgical process is to follow site standard of care for total knee arthroplasty. The approved surgical technique (specific to the configuration implanted and the instrumentation used) must be followed. Any deviation from the approved surgical technique must be reported as a protocol deviation. See Table 7-2 for further detail.

Table 7-2: Protocol Requirements During Surgery

Surgical Process detail	Protocol instructions
Instrumentation	• The manual arm of the study will use the ATTUNE Intuition Instrumentation (Reusable or SOLO). Computer assisted surgery, TruMatch technology or any other type of Custom Patient Instruments **is not permitted.** The surgeon will target placing the implant perpendicular to the mechanical axis of the leg but may vary by +/- 3 degrees if deemed advantageous to the soft tissue management of the knee. • The Robotic arm will use the VELYS Robotic-Assisted Solution supported by the ATTUNE Intuition instrumentation for the steps as indicated by the surgical technique. The surgeon will target placing the implant perpendicular to the mechanical axis of the leg but may vary by +/- 3 degrees if deemed advantageous to the soft tissue management of the knee.
Implant system	This investigation allows the Investigator to follow their current standard of care with respect to the choice of configuration of the ATTUNE system used including cemented CR FB, CR RP, PS FB, PS RP, or Cementless CR RP or PS RP (see section 10.2).
Patellar Treatment	This investigation allows the Investigator to follow their current standard of care with respect to patellar resurfacing. Specifically, the Investigator can choose to: • resurface the patella • leave the patella unresurfaced.

Data collected during the operative management of the Subject is listed in Table 7-1.

7.2.5 Post-operative Management

Immediate post-operative management including physical therapy protocol is at the discretion of the surgeon and support staff and should follow each Site's standard of care. Rehabilitation programs are often individualized, however, efforts should be made by the principal investigator to ensure that these programs remain consistent throughout the execution of the study.

The follow-up windows have been selected to achieve the primary objective of investigating the accuracy of the VELYS Robotic-Assisted Solution, as well as providing further data to characterize the patient recovery over the first post-operative year. Every effort should be made to schedule the post-operative follow-up within these windows to enhance follow-up compliance. While required interval windows have been designed to be continuous (with the exception of the first week after surgery) to improve follow-up compliance and accommodate various standards of care across sites, this study includes preferred

windows as well to increase the consistency with respect to the timing of data collection, since function is changing with time, particularly in the early recovery phase.

All follow-up visits will be conducted according to the Time and Events Table (Table 1-1), and applicable eCRFs must be submitted to the Sponsor.

Data collected during the post-operative management of the Subject is listed in Table 7-1.

7.2.6 Radiographic Procedures

Radiographic guidelines regarding image collection and transmission to the independent radiographic reviewer will be provided to the Principal Investigator. Weight bearing Long leg AP X-rays and lateral views are to be obtained pre-operatively and at the 12 week visit (baseline evaluation). Long leg AP X-rays are critical to be able to achieve the primary objective of assessing the alignment achieved. **Skyline views will not be collected in this study.**

7.3 Discontinuation of Subject Participation

Study participation may be discontinued through screen failure, not receiving the study treatment, revision of either the femoral component or metal tibial tray, withdrawal of consent, death or surgeon preference/ medical opinion (this should occur under very limited conditions, in order to avoid the investigator bias). Table 7-3 describes how data will be captured on Subjects that are discontinued prior to receiving the study treatment. In all cases, once a subject is enrolled (per Figure 7-1), if they discontinue study participation, a Subject Completion/Discontinuation eCRF must then be completed.

7.3.1 Enrollment Replacement Rules

Since subjects are enrolled at the time of consent, any subject that is withdrawn preoperatively will be replaced with a subsequent subject. Overall, the number of subjects who are enrolled and undergo a TKA procedure in the control group must meet the sample size of 100 subjects and the number of subjects who are enrolled and undergo a TKA procedure in the study group must meet the sample size of 100. For Intra-operative withdrawals the action will vary depending on the reason for the withdrawal or deviation per Table 7-3.

Table 7-3: Enrollment Replacement examples

Scenario	Data submitted on eCRF?	Example	Action
Pre-operative screen failure (discovered post-consent but pre-op)	Yes	*Subject withdrew consent or the Subject no longer met inclusion/ exclusion criteria.*	• Complete at a minimum inclusion/ exclusion criteria, Demographics, Medical History and surgical history eCRFs. • Complete Subject Completion/ Discontinuation eCRF • Recruit an additional subject

Scenario	Data submitted on eCRF?	Example	Action
Inclusion/exclusion criteria violation discovered post-op	Yes	*Too old*	• Keep as Subject – continue to follow as per protocol • Complete a Protocol deviation eCRF
Intra-operative withdrawal	Yes	*Did not use planned ATTUNE knee or planned process (manual or robotic) to implant the knee due to equipment not being available* *Or Investigator determined intra-operatively that the bone quality is insufficient to support planned procedure or they do not have sufficient access to the bony landmarks or the hip center of rotation cannot be established.*	• Complete Subject Completion/ Discontinuation eCRF • Recruit an additional subject
Intra-operative deviation	Yes	*Procedure started with robot (started executing bone cuts) then surgeon bails out to manual instruments midway through the procedure.*	• Consider submitting a Device Deficiency eCRF (depending on cause of change in surgical process) • Consider submitting AE eCRF (if event meets the definition of AE) • Complete a Protocol deviation eCRF • Keep as Subject – continue to follow as per protocol • Do not recruit another subject to replace

7.4 Post-operative Withdrawal of Enrolled Subjects

A post-operative withdrawal is a Subject who has signed the Informed Consent Document (ICD), has been implanted with a study device, and is later withdrawn from study participation (i.e., withdrawal of consent, revision of femoral or metal tibial components, death, etc.)

Table 7-4 describes post-operative withdrawal scenarios and the eCRF to be completed.

Further description of revision is provided in Section 7.6, Revisions/Reoperations. No data after the date of withdrawal will be included in the clinical analysis.

Table 7-4: Post-operative Withdrawal Scenarios

Example	Action	Follow Up
Subject withdraws consent/lost to follow up	• Study site documents Subject's request for withdrawal from study. • Complete Subject Completion/ Discontinuation eCRF	Do not continue
Death	• Complete Adverse Event eCRF • Complete Subject Completion/ Discontinuation eCRF	Do not continue
Revision	See Section 7.5 and Table 7-5 Revision Examples	

7.5 Revisions/Re-operations

A "revision" is defined as a surgical procedure of the affected knee where one or more of the TKA components (femoral component and/or metal tibial base, polyethylene insert, or patella polyethylene resurfacing component) are removed. Should it be necessary for the Subject to undergo a revision of either the femoral or metal tibial base between the time of enrollment and completion of the study data acquisition, the Subject is to be withdrawn from study participation. Thus, both an Adverse Event (AE) eCRF and a Subject Completion/Discontinuation eCRF must be completed. Note that if a tibial polyethylene insert is exchanged and/or a resurfaced patella is revised but both femoral and tibial components remain intact, then an AE eCRF must be completed but the subject is not to be withdrawn. Examples of how to handle revisions are shown in table 7-5.

Table 7-5: Revision Examples

Example	Actions	Follow Up
Removal / revision of metal tibial base and/or femoral component	Complete Adverse Event eCRF Complete Subject Completion/ Discontinuation eCRF	Do not continue
Tibial polyethylene exchange	Complete Adverse Event eCRF	Continue
Revision of a previously resurfaced patella	Complete Adverse Event eCRF	Continue
Resurfacing of a previously unresurfaced patella	Complete Adverse Event eCRF	Continue

A re-operation is defined as any surgical procedure of the affected knee in which no TKA components are removed. Examples include irrigation & debridement without tibial insert exchange or the resurfacing of a previously unresurfaced patella without tibial insert exchange. These subjects are not to be withdrawn. An Adverse Event (AE) eCRF must be completed.

7.6 Lost to Follow-up

Although follow-up compliance is essential to study quality, some Subjects may not be able to return for follow-up evaluations. Sites should make efforts to ensure complete follow-up including phone calls and written requests to a Subject as required. If these approaches are not successful, then the site may

document a Subject as lost-to-follow-up on the Subject Completion/Discontinuation eCRF. Contact attempts should be documented in the Subject's medical notes.

8 STATISTICAL METHODOLOGY

This section describes the statistical methods for the study design and planned analysis of study data.

8.1 Study Design

This study is designed as a prospective sequential controlled cohort study utilizing the ATTUNE knee. All procedures will be done either with traditional surgical instruments and cutting blocks (Manual Cohort) or with the VELYS Robotic-Assisted Solution (Robotic Cohort). Each site will enroll Subjects into the Manual Cohort until their enrollment target has been reached, and then will enroll Subjects into the Robotic Cohort.

8.2 Treatment Assignment

Each site is expected to implant approximately 10-20 ATTUNE knees in each of the control (Manual Cohort) arm and the study (Robotic Cohort) arm. There will be a maximum of 8 sites that will recruit a total of 200 Subjects (100 manual cohort and 100 in the Robotic cohort). Each site will use the implant configuration(s) that fit with their standard of care. Both resurfaced patella and non-resurfaced patella are permitted in this investigation, consistent with the site's standard of care.

Only one knee per subject will be included in the study. For bilateral subjects (staged) only the first knee implanted during study enrollment may be enrolled.

8.3 Randomization and Blinding Procedures

This is a non-randomized study. Surgeons will first perform their Manual Cohort cases followed by their Robotic Cohort cases. The purpose is to capture the current state of traditional, non-robotic procedures compared to robotic-assisted procedures. Following robotic-assisted procedures changes and improvements may be made to the standard of care with traditional, non-robotic instrumentation and would thus confound study comparisons.

Subjects may be unblinded to the type of instruments used in their case.

8.4 Interval Windows

The pre-operative assessment is to be done 90 days prior to the procedure up to day 0 (defined as the day of the index procedure for this study); radiographs for this study may be from 180 days prior to day 0 (or longer if the PI determines they are acceptable for surgical planning). The required window intervals for analysis purposes are defined as follows:

Table 8-1: Interval Windows

Required* Follow-up Intervals (days)			
Pre-op**	**Day 0**	**12 Weeks**	**1 Year**
-90 to 0d	0 (Defined as the Day of TKA)	7-182	183-547
* Although these are the windows for analysis purposes, narrower "preferred" interval windows have also been included in this protocol. ** Pre-operative radiographs may be in the window -180 to 0 days (or longer if the PI determines they are acceptable for surgical planning)			

Multiple visits within these defined windows for a single subject may occasionally occur. If this occurs then for both the pre-op and 12 week intervals the visit closest to the date of surgery will be considered the study visit. Individual pre-op data (i.e. radiographs, PROMs, etc.) may be collected at different pre-op visits and each type of data will be considered separately when considering multiple visits.

8.5 Levels of Significance

Where estimated, all confidence intervals will be 95% confidence intervals. For the primary endpoint hypothesis test an alpha = 0.05 will be used to determine statistical significance. No adjustments will be made for multiplicity as this is the only formal hypothesis in the study. Although there are no other formal hypotheses in this study, final results may be provided along with p-values to facilitate clinical judgement.

8.6 Analysis Sets

The following analysis sets are defined for the purpose of analysis: an Intent to Treat (ITT) analysis set, a Safety analysis set, and a Per Protocol (PP) analysis set. The analyses of adverse events and the Kaplan-Meier analysis of revisions will be carried out on the Safety analysis set. The primary endpoint analysis will be carried out on the ITT analysis set and all secondary endpoint analyses will be carried out on the Per Protocol analysis set. The analysis of the tertiary endpoints will be carried out on the PP analysis set unless otherwise stated in the final clinical summary report.

Enrolled subjects set who do not undergo surgery to implant the ATTUNE system with either manual instrumentation or with the VELYS Robotic-Assisted Solution will be withdrawn from the study without any further data collection, replaced per section 7.3.1 Enrollment Replacement Rules, and will not be included in any analysis set.

8.6.1 ITT Analysis Set

The ITT analysis set consists of all subjects who are consented, enrolled into the study, and undergo a TKA procedure with any cuts attempted with the intended device(s). The purpose of this analysis set is to perform the primary endpoint non-inferiority analysis. Analysis of the ITT set will be performed based on the intended instrumentation for the procedure.

8.6.2 Safety Analysis Set

The Safety analysis set consists of all ITT subjects who complete surgery to implant the ATTUNE primary TKA system with the intended instrumentation. Analysis of the Safety set will be performed based on the actual instrumentation used for the procedure.

All intraoperative events that occur before an intra-operative screen failure will be reported.

8.6.3 PP Analysis Set

The Per Protocol (PP) analysis set is a subset of the Safety analysis set that includes all subjects who meet the following criteria:

- There are no clinically meaningful deviations from the protocol eligibility criteria, and
- The subject receives an ATTUNE primary TKA system,
- The subject is implanted with the intended surgical instrumentation,
- The subject has at least one post-operative evaluation in the 6 week or later time window.

Analysis of the PP set will be performed based on the instrumentation used to complete the procedure.

8.7 Sample Size Justification

The primary endpoint analysis is a non-inferiority comparison of the mean of the absolute values of deviation from planned Hip-Knee-Ankle angle (HKA) with a non-inferiority margin of 1.5 degrees (as described in the Primary Endpoint section below). The study will be deemed to be successful if non-inferiority is successfully demonstrated using a t-test with a 1-sided alpha of 5%. Based upon an anticipated standard deviation of approximately 2.4 degrees in deviation from plan measurements, it is estimated that there is greater than 99% power to demonstrate non-inferiority in this primary endpoint analysis.

The sample size of N=100 has also been established to provide sufficient data for the evaluation of the nature, severity, and frequency of adverse events associated with the use of the Robotic system. Specifically, if a local serious adverse event is likely to occur in at least 5% of patients in the general population (as determined from review of previous ATTUNE total knee replacement studies using conventional instruments), then with a sample size of N=100 there is greater than a 99% chance of the observation of at least 1 such event in this study. There is greater than 80% change of observing at least one event for adverse events that occur with a rate of 1.6% or greater.

8.8 Analyses to be Conducted

8.8.1 General Conventions

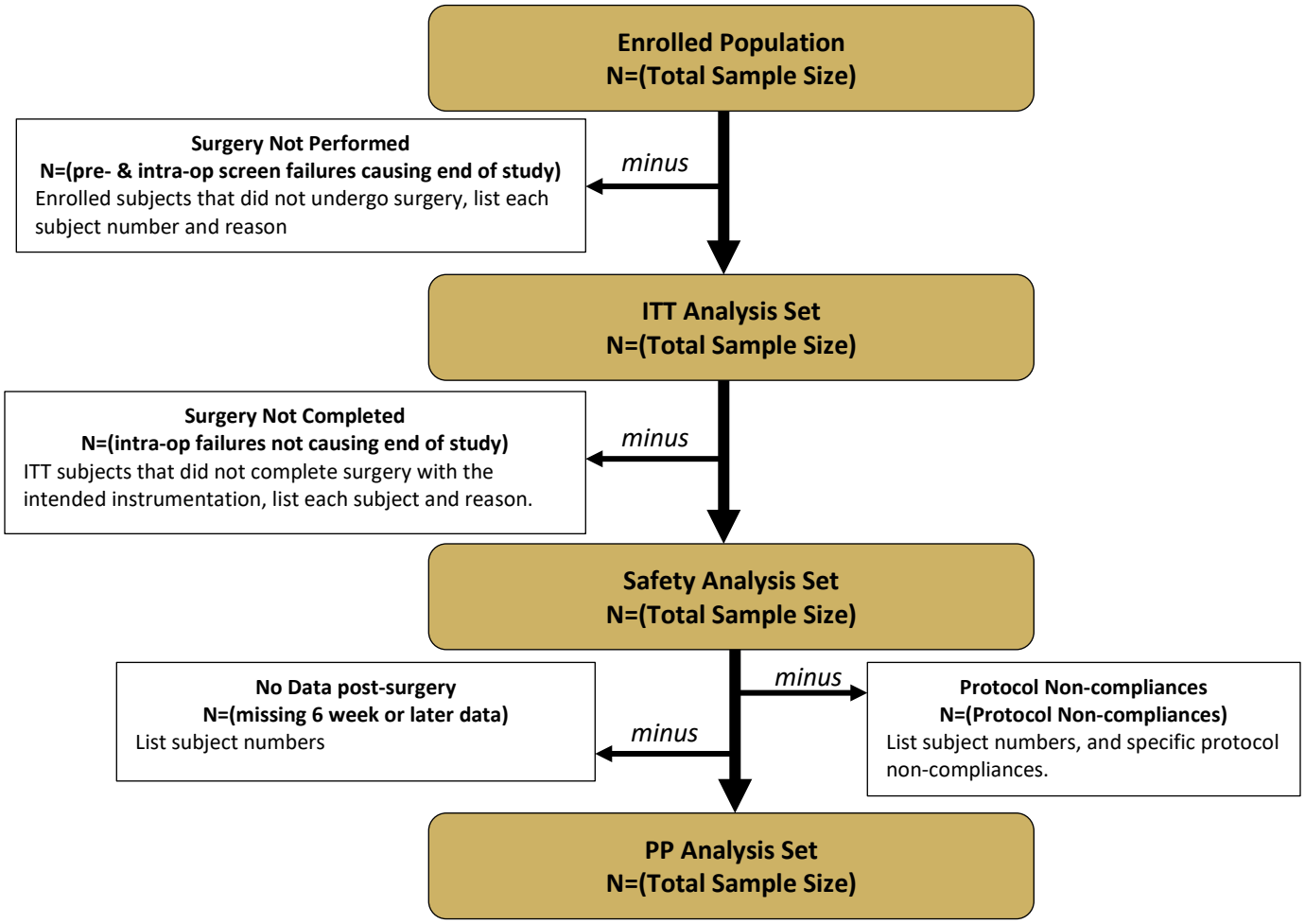
All analysis will be performed using SAS v9.4 or higher. Statistical summaries (tallies and percentages for categorical variables, and sample size, mean, standard deviation, minimum and maximum (and others as needed) for continuous variables) at each respective time point, or cumulatively for safety endpoints.

8.8.2 Disposition of Study Subjects

A detailed account of all enrolled subjects will be presented in a dataset flow diagram to display the analysis datasets, beginning with the set of ITT subjects and explicitly listing the subjects with

distinguishing reasons for exclusion from the other datasets. A template of this dataset flow diagram is given in Figure 8-1 below.

Figure 8-1: Analysis Set Flow Diagram



8.8.3 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized overall and by configuration. The demographics characteristics will be presented along with p-values to facilitate clinical judgement on any differences.

8.8.4 Primary and Secondary Endpoints and Associated Hypotheses

8.8.4.1 Primary Endpoint and associated hypotheses

The primary endpoint to evaluate accuracy to plan is a non-inferiority comparison of mean absolute value for deviation from planned HKA.

$$H_0: \mu_{Velys} - \mu_{Manual} \geq 1.5°$$

$$H_A: \mu_{Velys} - \mu_{Manual} < 1.5°$$

where μ_{Velys} is the mean absolute value of deviation from planned HKA for VELYS Robotic-Assisted Solution procedures, μ_{Manual} is the mean absolute value of deviation from planned HKA for procedures using manual instrumentation, and 1.5° represents the non-inferiority margin. Absolute value of the deviation from planned HKA angles will be calculated with the below calculation for both VELYS and Manual procedures:

absolute value deviation from plan = |*radiographic HKA – planned HKA*|

HKA measurements may be either positive or negative depending on varus/valgus alignment. The radiographic HKA is measured via the long leg, weight bearing X-ray at 12 weeks. The planned HKA for the Robotic procedures is the final planned HKA as determined via the robotic procedure workflow prior to making bone cuts.

Non-inferiority will be tested using a two-sample t-test with a 1-sided alpha of 5%. If non-inferiority is successfully demonstrated, then the study will be deemed to be successful, and a test for superiority of accuracy to plan achieved with VELYS Robotic-Assisted Solution (i.e. test margin of difference of 0°) will be conducted.

8.8.4.2 Secondary Endpoints and associated hypotheses

- Summarize the nature, severity, and frequency of local adverse events associated with the use of the Robotic system in total knee arthroplasty during the procedure and within the subsequent 12 weeks, 90 days[3] and 1 year.
- Summarize Intra-operative clinical assessment of soft tissue damage in both Manual and Robotics cohorts. The condition and function of the key knee structures (medial collateral ligament (MCL), lateral collateral ligament (LCL), posterior cruciate ligament (PCL), patella tendon (PT), posterior lateral capsule (PLC) and posterior medial capsule (PMC) will be assessed intra-operatively. The proportion of subjects that are uncompromised and fully functional for each structure will be presented along with a Fisher's extract test p-value to facilitate clinical judgement on any differences.
- If Per Protocol population differs from ITT population then perform the non-inferiority and superiority tests as specified above on the Per Protocol population.

[3] This is a specific analysis of data to determine number of AEs that occurred within 90 days of the procedure determined at 1year follow up – there is no 90 day visit.

- Summarize the alignment outliers (long leg alignment >3 degrees outside of plan) in both Manual and Robotics cohorts. Manual and Robotics cohorts will be presented along with a Fisher's extract test p-value to facilitate clinical judgement on any differences.
- Summarize surgical time for the Robotics and Manual cohorts; including skin-to-skin time and resection execution. Mean surgical time will be presented along with a two-sided sample t-test p-value to facilitate clinical judgement on any differences.
- Summarize individual component alignment achieved with manual instruments and Robotics in the frontal and sagittal planes, specifically: distal femoral varus-valgus (FM), proximal tibial varus-valgus (TM), femoral component flexion and tibial slope. Mean alignment measures will be presented along with a two-sided two sample t-test p-value to facilitate clinical judgement on any differences.

8.8.4.3 Additional Endpoints (Exploratory)

- Summarize the patient reported outcomes (EQ-5D, KOOS, FJS, Patient Knee Pain and Satisfaction) for the Robotics cohort vs. the Manual cohort by visit.
- Summarize the length of hospitalization/stay for the Robotics cohort vs. the Manual cohort.
- Summarize the discharge location for the Robotics cohort vs. the Manual cohort.
- Investigate impact of surgeon learning curve on the Robotic system on accuracy of surgical procedure (assessed via accuracy to plan of axis alignment measurements), patient reported outcomes, safety, and surgical time.
    - The mean of the first 10 procedures within a surgeon will comprise the learning curve cohort and will be compared to the later procedures.
    - Cut-off points other than the first 10 procedures (such as the first 3, or the first 5 procedures) and statistical models may also be used to explore the size and effect of any potential learning curve.

For the Robotics cohort there will be the following additional exploratory regression analyses. Each pair of variables below will be regressed on each other. The first variable (y) will be regressed on the second variable (x). The regression function, R-squared value, and the Pearson correlation will be estimated for each pair.

- the post resection long leg alignment recorded on the VELYS Robotic-Assisted Solution case report and the planned long leg alignment.
- the long leg alignment measured via weight bearing X-ray at 12 weeks and the post resection long leg alignment recorded on the VELYS Robotic-Assisted Solution case report.
- the post resection medial gap in extension recorded on the VELYS Robotic-Assisted Solution case report and the planned medial gap in extension.
- the post resection lateral gap in extension recorded on the VELYS Robotic-Assisted Solution case report and the planned lateral gap in extension.
- the post resection medial gap in flexion recorded on the VELYS Robotic-Assisted Solution case report and the planned medial gap in flexion.
- the post resection lateral gap in flexion recorded on the VELYS Robotic-Assisted Solution case report and the planned lateral gap in flexion.

- the thickness of the tibial insert implanted as recorded in the device log and the post resection medial gap in flexion.
- the thickness of the tibial insert implanted as recorded in the device log and the post resection lateral gap in flexion.
- the thickness of the tibial insert implanted as recorded in the device log and the post resection medial gap in extension.
- the thickness of the tibial insert implanted as recorded in the device log and the post resection lateral gap in extension.

For the Robotics cohort summarize the nature and frequency of device deficiencies associated with the use of the Robotic system in total knee arthroplasty during the procedure.

8.8.5 Plans for Interim Analysis

There are no plans for a formal interim analysis to evaluate early stopping of the trial.

Summaries of the procedural data for manual instrumentation procedures may be produced after all subjects have been enrolled and surgeries completed.

All secondary and tertiary endpoints associated with the surgery or a specific follow-up time point may be analyzed any time after all subjects have the visit window for that time point.

Complications will be monitored continuously to assure that unexpected adverse event rates are identified as soon as they become evident.

8.8.6 Handling of Missing Data

Only actual data will be analyzed; there will be no imputation of missing data.

9 RISK ANALYSIS

9.1 Anticipated Adverse Events / Non-Reportable Adverse Events

There are particular immediate 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 Expected/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 unless in the opinion of the investigator the event is directly related to the use of the Robotic System.

9.2 Study Related Risks/Reportable Adverse Events

Any surgical procedure poses a potential risk and the procedures undertaken as part of this clinical investigation are no exception. There are known risks associated with the method of anesthesia (general, epidural, local). In addition, there are risks associated with implantation of a device. The risks associated with the use of the robotic system in the study arm and the manual instruments in the control arm are

similar to those associated with conventional TKA surgery. The following are generally the most frequently reported AEs and complications in total knee arthroplasty. The AEs identified below (Table 9-1) are to be reported as AEs.

Table 9-1: Most Frequently Reported Adverse Events and Complications

General	• Early or late loosening, tibial subsidence, bending, cracking, fracture, deformation, or wear of one or more of the prosthetic components, often related to factors listed under WARNINGS AND PRECAUTIONS in the implant IFU. Loosening may also occur due to improper fixation or positioning. • Early or late infection which may require removal of the implant. • Pain, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, caused by improper positioning, looseness or wear of components. • Excessive wear of the polyethylene components due to intraoperative damage to the femoral component, loose cement and/or bone fragments, and/or high patient activity levels or weight. • Fractures of the tibia or femur. Intraoperative fractures are usually associated with revision surgery, deformity and/or severe osteoporosis. Postoperative fractures are usually stress fractures. Fractures can be the result of defects in the cortex due to multiple pin holes, prior screw holes, misdirected reaming, and/or inadequate or maldistribution of bone cement. • Cardiovascular disorders and thromboembolic disease, including venous thrombosis, and pulmonary embolus, and heart attack. • Tissue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergy or wear debris or loose cement particles. • Myositis ossificans, especially in males with hypertrophic arthritis, limited preoperative range of motion and/or previous myositis. The incidence of myositis ossificans is increased with a history of prior surgery and in cases of infection.
Early Post-operative Study Related Adverse Events	• Hematoma • Delayed wound healing or wound dehiscence • Varus-valgus deformity
Late Post-operative Study Related Adverse Events	• Inadequate range of motion due to improper selection or positioning of components, impingement and/or periarticular calcification. • Periarticular calcification or ossification, with or without impediment to joint mobility. • Patellar bone fracture as a result of excess tension or inadvertent intra-operative weakening. • Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy.

9.3 Benefit Analysis

For subjects within the study arm, the study device (VELYS Robotic-Assisted Solution) aims to result in a more precise, repeatable surgery reducing the risk of poor implant placement and the associated poor outcomes but these benefits are not yet proven. For subjects within the control arm they will benefit from

receiving additional rigor on their follow up compared to standard of care potentially resulting in faster identification and reporting of adverse events allowing faster resolution/treatment.

9.4 Adverse Event Reporting

Table 9-2: Adverse Event definitions

Term	Details
Adverse Event (AE)	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 a medical device. Adverse Event is synonymous with complication or medical event.
Serious Adverse Event (SAE)	An Adverse Event that led to any of the following: • death, • serious deterioration in the health of the Subject that, resulted in any of the following: • life-threatening illness or injury, • permanent impairment of a body structure or a body function, • hospitalization or prolongation of existing hospitalization, • medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function, • fetal distress, fetal death or a congenital abnormality or birth defect. Note: Planned hospitalization for a pre-existing condition, or a procedure required by the Clinical Investigational Plan, without serious deterioration in health, is not considered a serious adverse event.
Expected/ Anticipated	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.
Awareness (Date of AE Awareness)	The day, month and year that the study site becomes aware of information from any source that reasonably suggests that an Adverse Event has occurred. Note: This date may or may not correspond to the date of onset. The date of awareness is critical to reporting timelines (see Section 1.6).
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 associated with the VELYS Robotic-Assisted Solution, 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.

9.4.1 Adverse Event Reporting Guidelines

This protocol requires each site to comply with all adverse event reporting requirements of their respective IRB/EC's. For this protocol, not all AEs are required to be recorded in the eCRF and reported to the Sponsor. The below list are the reportable AEs that must be recorded on the eCRF and submitted to the Sponsor as soon as the site becomes aware:

- All SAEs, regardless of relationship, and
- All AEs related to the Device and/ or procedure, except for those listed in Exhibit A

Table 9-3: Adverse Event Reporting

Type of Adverse Event	Reporting Timeline
All SAEs	As soon as site becomes aware but no later than 72 hours after awareness
All Device Related AEs	As soon as able but no later than 2 weeks from site awareness
All Procedure Related AEs, except for those listed in Exhibit A	As soon as able but no later than 2 weeks from site awareness

The Investigator will record the nature, severity, seriousness, treatment and outcome of the AE, and will determine the association to the device and/or the study procedure.

Determination of Relationship: The determination whether the AE is related to the device (ATTUNE or VELYS Robotic-Assisted Solution) and/or procedure will be conducted by the Investigator based upon whether a causal relationship between the device and/or procedure and the AE is 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 be rated as follows:

1) Not related (definitely not related): there is no relationship between study device and/or procedure and the event.

2) Possibly related (remote possibility, possibly, or probably related): the relationship between study device and/or procedure could exist if there is no contradicting evidence that can reasonably explain the Subject's condition.

3) Causal relationship (definitely related): the relationship between study device and/or procedure and event does exist and is confirmed upon further investigation by the Investigator.

The following categories of AE severity to be used are presented in Table 9-4 below:

Table 9-4: AE Severity definitions

mild	awareness of a sign, symptom or event that is easily tolerated and transient in nature with minimal or no impairment to normal activity.
moderate	moderate symptoms that are poorly tolerated, sustained, interfere with normal activity and require medical attention.
severe	symptom(s) require intervention, and the activities of daily living are significantly altered.

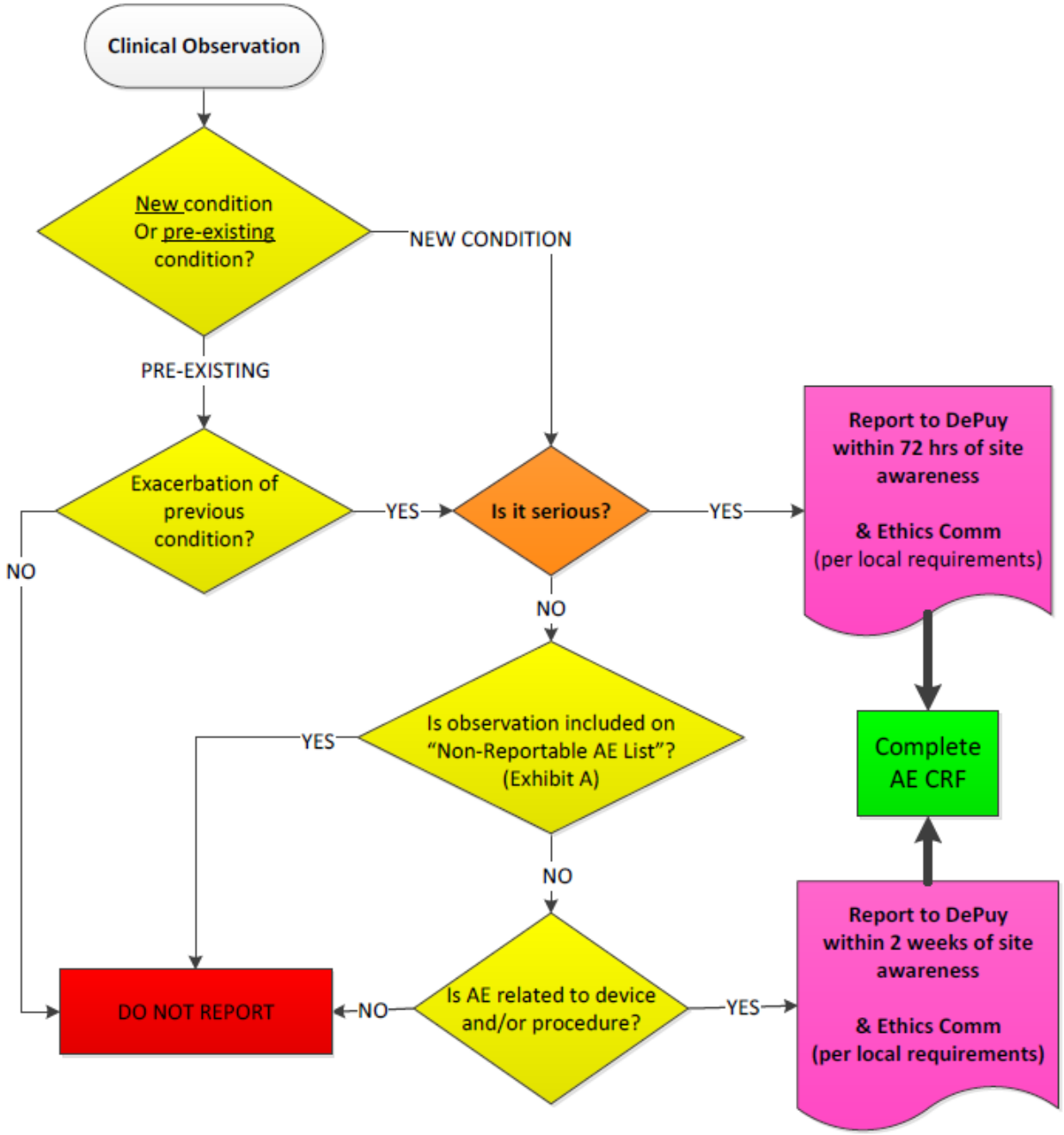
Pre-existing medical conditions or symptoms reported prior to device implantation are not to be recorded as AEs. In the event there is an exacerbation of the pre-existing medical condition or symptoms, then an AE must be reported.

As described above, all SAEs, all device related AEs and all procedure related AEs [with the exception of the Anticipated Adverse Events listed in Exhibit A] (refer to section 9.1) are required to be recorded on the AE eCRF beginning from the time of the initiation of the surgery until Subject participation has ended (study completed or withdrawal). AEs must be followed to resolution, or until the study completion or consent withdrawal. When an AE status changes (worsens, resolves), the AE eCRF should be updated to reflect the new information. When a Subject ends participation in the trial (either study completion or consent withdrawal) an AE must be designated either as "resolved" (end date must be provided), or as "ongoing."

Subjects should be encouraged to report AEs spontaneously and may volunteer AE information at any time. At each evaluation, the Investigator will determine whether an AE has occurred that meets the requirements for reporting in this study. If it is determined that an applicable AE has occurred, the Investigator should obtain all the information required to complete the appropriate AE form eCRF. If an event occurs at an outside institution, the Investigator should attempt to obtain, if possible, required AE information.

Figure 9-1: 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.



9.5 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. The Medical Monitor may contact the PI should questions

exist related to the determination of the event. All AEs reported to the Sponsor will be reviewed by the Sponsor and reported if applicable to the appropriate regulatory body.

Should an IRB/EC decide to suspend or withdraw its approval for an Investigator to conduct the study at that institution, based on unacceptable risks to the study Subjects, the study Sponsor will notify all reviewing IRB/ECs and Investigators of this action. To further minimize risks, any new information obtained during the study relating to unanticipated adverse findings (that is those not mentioned in any of the IFU, this CIP or Exhibit B) will be provided to all Subjects, Investigators, and IRB/ECs.

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 from its surgical use will further control risks. In addition, only trained orthopaedic surgeons with expertise in treating this condition will conduct surgeries.

10 DEVICE DESCRIPTION

The intended purpose, indications, contraindications and population are described in the Instructions for Use (IFU), which is contained in the packaging and the associated surgical technique. The instrumentation is the primary focus of this study but the associated implants are included and their performance will also be assessed by default.

10.1 Surgical Instruments

Surgical instruments aid the surgeon in the execution of bone preparation to allow the implantation of the TKA implant components. The study design consists of two arms; the study arm will utilize the VELYS Robotic-Assisted Solution in combination with the manual ATTUNE Intuition instruments to support the implantation of the ATTUNE Knee whilst the control arm will only use the manual ATTUNE Intuition instruments to support the implantation of the ATTUNE Knee.

10.1.1 VELYS Robotic-Assisted Solution

The VELYS Robotic-Assisted Solution assists the surgeon in the execution of the bone resections required during TKA. The system uses a stereotaxic methodology whereby marker arrays reference and track the position of the femur, tibia and instrumentation to generate a surgical plan on the graphical user interface based on the surgeon's instructions/preferences. The robotic-assisted device then moves the saw into position and controls the plane of the resection (according to the plan) whilst the surgeon executes the resections, once the resection is complete the robotic-assisted device then moves onto the next resection. It is intended that this system/method will result in greater precision and accuracy in the execution of these resections. Once the resections (distal femoral, proximal tibia and femoral anterior, posterior and chamfer) are executed by the system the ATTUNE Intuition manual instruments are used to complete the remainder of the procedure including preparation of the tibia, femoral finishing, patella prep (if resurfacing) and trialing. The VELYS Robotic-Assisted Solution is only indicated for use with the ATTUNE Total Knee system. The products codes associated with the system are listed in EXHIBIT C.

10.1.2 ATTUNE Intuition Instruments (Manual Instruments)

The ATTUNE Intuition Instruments were developed to aid the implantation of the ATTUNE TKA implants. The system includes jigs/fixtures that reference anatomical landmarks and help the surgeons to position a series of cutting blocks which are pinned to the bone and guide the surgeon to execute the resections with a sawblade/saw console. Once the resections are executed, other instruments are used to complete the final bone preparation to prepare for the implants before finally trial components are used whereby the surgeon can check he has used appropriately sized components and achieved 'balanced' soft tissues.

10.2 Implants

The implants to be used in this study are the ATTUNE total knee system. There are many different configurations of the ATTUNE Knee system (see Table 10-1). Depending on the standard of care, each site may use different configurations of the system but are required to remain consistent in the selection criteria between the two study arms. e.g. if the investigator at a site uses the ATTUNE cemented CR FB knees by default for every case, they should use this same construct for both the control and study arm. The product codes of the implants are listed in EXHIBIT D.

Table 10-1: Detailed Device Information for ATTUNE Implants

Device Component	Component offerings		Details
Femoral Components	Cruciate Retaining (CR)	Cemented	ATTUNE femoral components are available in **cruciate retaining (CR)** and **posterior stabilized (PS) configurations**. The femoral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM standard F-75. They are available in lefts and rights. Fourteen sizes are available including standard sizes 1-10 and narrow sizes: 3N, 4N, 5N, 6N. Femoral components are sterilized using gamma irradiation**.** The PS femoral components have a cam mechanism that articulates with a corresponding spine on the PS tibial insert. Both the CR and PS configurations are available in cemented and Cementless designs with the Cementless designs including a porocoat coating to facilitate cementless fixation.
		Cementless	
	Posterior Stabilized (PS)	Cemented	
		Cementless	
Tibial Bases	Fixed Bearing (FB)	Cemented	The FB cemented tibial bases are manufactured from Co-Cr-Mo alloy conforming to ASTM standard F-75. The proximal surface has a universal locking feature that is used for securing the FB tibial insert and permits up-sizing and downsizing. Ten sizes are available including 1-10. The cemented components have a blasted finish to provide for enhanced cement fixation. FB Tibial Bases are sterilized using gamma irradiation**.**

Device Component	Component offerings		Details
	Rotating Platform (RP)	Cemented	The RP tibial bases are manufactured from Co-Cr-Mo alloy conforming to ASTM standard F-75. The metal bases have a hollow, conical intramedullary stem. The flat superior surface of the base has a central hole continuous with the hollow conical medullary stem which receives the conical spike of the RP tibial insert components. The RP tibial insert component is not secured to the metal base but rotates axially to maintain congruent contact with the femoral prosthesis. Ten sizes are available including 1-10. The cemented RP base is offered only in a keeled version. The RP base articulates with the RP CR and RP PS tibial inserts. The cemented components have a blasted finish to provide for enhanced cement fixation. RP Tibial Bases are sterilized using gamma irradiation. The Cementless design includes a porocoat coating on the distal surface to facilitate cementless fixation and features a central cone and four pegs.
		Cementless	
Tibial Inserts	Fixed Bearing (FB)	Cruciate Retaining (CR)	The CR and PS tibial inserts are manufactured from UHMWPE and are available in sizes 1-10 and thicknesses from 5, 6, 7, 8, 10, 12, 14, 16, 18mm. Additional thicknesses 20 & 22mm are available for the PS inserts. The distal surface has features that secure the insert to the FB tibial base. Tibial inserts are sterilized using gas plasma sterilization. The PS insert has a spine which articulates with the cam on the corresponding PS femoral component.
		Posterior Stabilized (PS)	
	Rotating Platform (RP)	Cruciate Retaining (CR)	CR and PS inserts are manufactured from UHMWPE and are available in sizes 1-10 and thicknesses from 5, 6, 7, 8, 10, 12, 14, 16, 18mm. Additional thicknesses 20 & 22mm are available for the PS inserts. RP inserts should be the same size as the selected femoral component. The RP inserts articulate with the RP primary bases and should be within 2 sizes of the RP tibial base. Tibial inserts are sterilized using gas plasma sterilization. The CR RP insert can be used with or without an intact PCL. The PS insert has a spine which articulates with the cam on the corresponding PS femoral component.
		Posterior Stabilized (PS)	
Patellae	Medial Offset	Cemented only	Patellar components are manufactured from UHMWPE. They are available in two styles, medialized dome and medialized anatomic. They are available in 5 sizes with proportionally increasing thicknesses from 8.5 to 10.5 mm.
	Anatomic		

11 INVESTIGATOR RESPONSIBILITIES AND GOOD CLINICAL PRACTICES

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

- Ensuring that a clinical investigation is conducted according to the Declaration of Helsinki, applicable local regulations, the signed statement of Investigator, and the Clinical Investigation Plan;
- Protecting the rights, safety, and welfare of Subjects under the Investigator's care;
- Ensuring the integrity of the data; and
- Ensuring that they have participated on the appropriate training for the devices used in this study.

Prior to the initiation of this clinical investigation at each site, the responsible Principal Investigator will acknowledge their understanding of this Clinical Investigation Plan (CIP) by signing the signature page.

11.1 Institutional Review Board (IRB)/Ethics Committee (EC) Approval

All Principal Investigators must submit to their institution's IRB/EC for initial review a copy of the clinical investigational plan (CIP) and a sample Informed Consent Document (ICD) provided by the Sponsor. Many institutions request modification of the ICD to satisfy specific institutional requirements. The use of a modified or unique Informed Consent Document is permitted provided that the document is reviewed and approved by the Sponsor.

All Principal Investigators must submit the Clinical Investigation for continuing review and any other additional required submissions to their IRB/EC according to their IRB/EC's policies and procedures.

Initial approval/favorable opinion and all continuing review approvals must be documented; originals of correspondence and approvals are to be filed by the Investigator and copies forwarded to the Sponsor.

11.2 Informed Consent

The Principal Investigator is responsible for maintaining source documents evidencing informed consent was obtained from study Subjects prior to participation in the study and the process followed to obtain consent.

The Principal Investigator is responsible for taking the necessary steps to collect, process, and maintain confidentiality of the study Subject's personal data in accordance with data protection legislation including the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Subjects will be asked to sign an Authorization for Release of Protected Health Information (PHI) for the purpose of this in investigation. This authorization may be combined with the ICD depending on local IRB preference.

If an Investigator performs any study-specific data collection without obtaining written informed consent, the Investigator will promptly report such use to the Sponsor after becoming aware of such a non-compliance and the reviewing IRB/EC per their procedures.

For further details and a description of the Informed Consent process, please refer to Section 7.1.2, Subject Informed Consent.

11.3 Protected Health Information

The Principal Investigator is responsible to inform study Subjects their personal data will be collected, processed, and confidentially maintained in accordance with local data privacy regulation and law. Data protection consent will be obtained from the Subjects as part of the informed consent process.

Results from the Clinical Investigation may be published. However, Subject confidentiality will always be maintained, and it will not be possible to identify individual Subjects from any data presented.

11.4 Subject Discontinuation from the Clinical Investigation

Any Subject is entitled to discontinue/withdraw from this clinical investigation for any reason without obligation and/or prejudice to further treatment. In addition, the Investigator may decide, for reasons of medical prudence, to withdraw a Subject.

The Investigator will clearly document the date and reason(s) for the Subject's discontinuation from this clinical investigation in the eCRF and submit to the Sponsor.

Please refer to Section 7.3 Discontinuation of Subject Participation for further details.

11.5 Source Documentation

The Investigator will maintain a complete, current and accurate case history (Source Documentation records) on each study Subject according to the usual procedure at the investigational site. Case histories typically include medical records, including progress notes, hospital charts, nurses' notes etc. Additional documents to be retained include:

- Signed original Informed Consent Document
- Executed Authorization for Release of Personal Health Information (may be combined with Informed Consent Document based on local IRB/EC requirements)
- Completed Source worksheets (if used)
- Results of relevant diagnostic and laboratory tests
- Intraoperative and post-operative complications and treatment, and
- Any other relevant information or documentation pertaining to the condition of the Subject.

The Investigator should retain copies of all documents pertaining to this clinical investigation (for at least 3 years in the United States after this clinical investigation is completed, or according to institutional policy if longer. In addition, if the Investigator moves/retires, etc., s/he should provide the Sponsor with the name and address of the person who will be responsible for the Subjects' clinical investigation related records.

Monitors may verify data reported in the electronic data capture (EDC) system with site source documents. The Investigator agrees that the Sponsor's employees or designees will have the right to audit and review pertinent medical records relating to this clinical investigation and the Subject will grant approval for such access to his/her medical records via the Informed Consent process.

11.6 Record of Device Inventory

As this is a Post-Market Study, there is no regulatory requirement to record device inventory, however, product that is supplied to the sites by the Sponsor specifically for the purposes of conducting the study will be tracked in an accountability log at each site.

11.7 Case Report Form Completion and Data Submission

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. 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 Guidelines (eCCGs), 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.

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 the Sponsor. 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.

11.8 Protocol Adherence

The Investigator(s) agrees to conduct the study in accordance with this protocol. Prior to beginning the study, the Investigator(s) must sign the protocol signature page.

An Investigator must not make any changes in a study without first receiving approval from the Sponsor and IRB/EC, except when necessary to eliminate apparent immediate hazards to a Subject.

Except for emergency situations, no deviations to this CIP will be permitted. In the event of an emergency situation, the Investigator must notify the Sponsor immediately. The Site will be responsible for completing a Protocol Deviation form within the EDC system, which will serve as Sponsor notification. The appropriate IRB/EC will be notified as applicable in accordance with their respective requirements. Protocol deviations cover all departures from the protocol including but not limited to: missed study visits, missing radiographic views, late reporting of adverse events, informed consent documentation issues, improper informed consent.

11.9 CIP Amendments

If it becomes necessary to amend the Clinical Investigation Plan then the nature of the amendment will be agreed between the Sponsor and the Principal Investigator(s) and this will be recorded with a justification for the amendment. The appropriate IRB/EC, will be informed of any amendments.

11.10 Reports

In fulfillment of study related requirements, the Investigator is responsible for preparing and submitting complete, accurate, and timely reports as described below.

Table 11-2: Investigator Reporting Responsibilities

Report	Description	Action
Withdrawal of IRB/EC approval	The Investigator will promptly notify the sponsor of a withdrawal of approval by the reviewing IRB/EC or of the investigator's part in an investigation within 2 weeks.	Preferably within 2 weeks
Progress Report	If required by his/her IRB/EC, the investigator is responsible for submitting progress reports on the investigation to the reviewing IRB/EC.	As required per IRB/EC requirements

Report	Description	Action
Reports of deviations from the investigational plan	The Investigator will notify the Sponsor of any deviation from the Investigational Plan as soon as able. The Investigator will notify the IRB/EC of any deviation from the Investigational Plan per the IRB/EC requirements.	As required per IRB/EC requirements
Other	The Investigator will, upon request of a reviewing IRB/EC or Sponsor, provide accurate, complete, and current information about any aspect of the investigation.	As requested

The Principal Investigator may delegate a qualified associate(s) to complete one or more of the above functions. However, the Principal Investigator retains the overall responsibility for Subject safety, proper conduct of the study including obtaining Subject Informed Consent, compliance with this study plan, and the collection of all required data.

11.11 Investigator Site File

Each Investigator and all personnel from the investigational site 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 and correspondence: electronic, written, and verbal, relating to any aspect of the clinical investigation.

The Investigator Site Files (ISFs) may be kept in paper or electronic format, however at any one time only one format should be used for the ISF at any particular site. The records are maintained in the Investigator Site File consisting of, but not limited to, correspondence with other participating Investigators, the reviewing IRB/EC, and the Sponsor.

Upon receipt of copies of changes or revision updates to the Clinical Investigation Plan (otherwise known as the Study Protocol) from the Sponsor, the Investigator will add the updated document and Revision Log to the Investigator Site File. The outdated version will be filed.

11.12 Investigator Study Termination

The Investigator may prematurely terminate the clinical investigation at any time. Should this be necessary, the procedures will be arranged on an individual clinical investigation basis after review and consultation by both parties. In terminating the clinical investigation, the Sponsor and the Investigator will assure that adequate consideration is given to the protection of the Subject's interests, all documentation is archived and the appropriate bodies such as the IRB/EC are informed as appropriate.

12 SPONSOR OBLIGATIONS

12.1 IRB/EC Approval

The Sponsor requires this Clinical Investigation Plan to be submitted to the IRB/EC for initial review and approval before implementation at each site. Additionally, all protocol amendments must be submitted to the IRB/EC for review and approval before implementation.

Each site is required to submit a copy of the IRB/EC initial approval, and any subsequent renewals to the Sponsor for filing in the study's Trial Master File. The site is to maintain the original documentation of the initial approval and renewals in the site's Investigator Site File.

12.2 Investigator Training, Study Initiation

Prior to enrolling Subjects in this study, the Investigator and/or appropriate site personnel will be trained on the study protocol to include:

• the general aspects of study administration,

• all procedures in the protocol, and

• the procedure for e-data acquisition and transmission.

The Sponsor will be offering hands on training to supplement professional education of the surgeon on the implant and surgical instruments, as needed.

12.3 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.

If under certain circumstances (i.e. limited access for sponsor study personnel to hospitals due to Covid-19 pandemic) on site monitoring is not possible, Sponsor may plan for remote monitoring and source data review or verification, where applicable. Details will be described in the study specific documents, such as monitoring plan, or other applicable documents.

12.4 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.

In the event of the study being terminated, any enrolled Subjects that have not yet had the surgical procedure would be treated as per their surgeon's standard practice using implants and instruments of the surgeon's choice. Each enrolled Subject would continue to be cared for by his/her surgeon according to his/her standard of care. No further study-related procedures or data collection would occur.

13 Investigational Plan EXHIBITS

Exhibit	Description of Exhibit
A	Listing of Anticipated Adverse Events
B	References
C	Product codes of the VELYS Robotic-Assisted Solution
D	Product codes of the ATTUNE Implants

EXHIBIT A: Non-Reportable 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, 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 38.3°C / 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 38.3°C / 101°F)

If you have any questions about potential adverse events or adverse event reporting, then please contact the Sponsor.

EXHIBIT B: References

1. Kurtz, S., et al., *Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030.* J. Bone Joint Surg. Am, 2007. **89**(4): p. 780-785.
2. Labek, G., et al., *Revision rates after total joint replacement: cumulative results from worldwide joint register datasets.* J Bone Joint Surg Br, 2011. **93**(3): p. 293-7.
3. Sharkey, P.F., et al., *Why are total knee arthroplasties failing today--has anything changed after 10 years?* J. Arthroplasty, 2014. **29**(9): p. 1774-1778.
4. Insall, J.N., et al., *Total knee arthroplasty.* Clin Orthop Relat Res, 1985(192): p. 13-22.
5. Krackow, K.A., et al., *A new technique for determining proper mechanical axis alignment during total knee arthroplasty: progress toward computer-assisted TKA.* Orthopedics, 1999. **22**(7): p. 698-702.
6. Jeffery, R.S., R.W. Morris, and R.A. Denham, *Coronal alignment after total knee replacement*, in *The Journal of bone and joint surgery. British volume J Bone Joint Surg Br*. 1991. p. 709-714.
7. Hungerford, D.S. and K.A. Krackow, *Total joint arthroplasty of the knee.* Clin Orthop Relat Res, 1985. **192**: p. 23-33.
8. Fang, D.M., M.A. Ritter, and K.E. Davis, *Coronal alignment in total knee arthroplasty: just how important is it?* J Arthroplasty, 2009. **24**(6 Suppl): p. 39-43.
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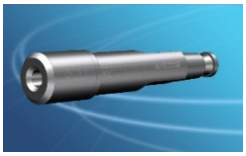
EXHIBIT C: PRODUCT CODES OF THE VELYS ROBOTIC-ASSISTED SOLUTION

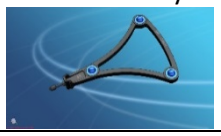
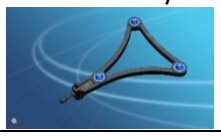
Hardware

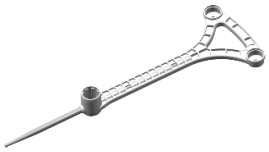
Product Code	Description	Picture	Sub Assemblies	
451570100	Base Station		Footswitch	
			Power Cable	
			Camera	
			Touchscreen	
			Main Console	
			Robotic-assisted Device Console	
			Saw Console	
			Cart	
451570101	Satellite Station		Satellite Station Touchscreen	
			Satellite Station Console	
			Satellite Station Transfer	
			Satellite Station Cart	
			Satellite Station Cable	
			Robotic Assisted Device	Actuation Unit
				Planar Articulation
			Holding Arm US Standard	Holding Arm Horizontal Adjustment
				Holding Arm Vertical Adjustment

Accessories – Reusable Instruments

Product Code	Description	Picture
451570102	Saw Handpiece	
451570105	Saw Interface Left	
451570106	Saw Interface Right	
451570107	Array Clamp	
451570108	Array Drill Pin Inserter	

Accessories – Single Use Instruments

Product Code	Description	Picture	
451570000	Oscillating Saw Blade		
451570001	Array Set -Knee	Femur Array 	Tibia Array 
		Saw Array 	Device Unit Array 
		Plane Checker 	Pointer 
451570203	Array full set Knee	Femur Array (PIM) 	Tibial Array (PIM)_ 
		Saw Array 	Device Array (PIM) 
		Pointer 	

Product Code	Description	Picture	
451570011	Array Set Knee	Femur Array (PIM) 	Tibial Array (PIM)_ 
		Saw Array (PIM) 	Device Array (PIM) 
		Pointer (PIM) 	
451570012	Metal Plane Tool		
451570004	Array Drill Pin 100 mm x 4 mm		
451570005	Array Drill Pin 125 mm x 4 mm		
451570006	Array Drill Pin 175 mm x 4 mm		
451570008	Actuation Unit Sterile Drape (20 pack)		
451570009	Satellite Station Sterile Drape (20 pack)		

Additional Accessories

Product Code	Description
869188	Patellar Caliper
129901054	CAS Ligament Tensor Handle
129901055	CAS Tensor Spacer 5 mm
129901056	CAS Tensor Spacer 10 mm
129901080	CAS Ligament Tensor Size: 2
129901081	CAS Ligament Tensor Size: 4
254500049	Patella Femoral Lug Drill
480000100	DePuy Synthes Instrument Case Base
480010000	DePuy Synthes Instrument Case Lid
200420933	ATTUNE Trumatch Half Lid
254501700	ATTUNE DePuy Synthes Lid
451570232	VELYS Instrument Case

EXHIBIT D: PRODUCT CODES OF THE ATTUNE IMPLANTS

Product Code	Description
1504-00-101	ATTUNE CR Cemented Femoral Size 1 Left
1504-00-102	ATTUNE CR Cemented Femoral Size 2 Left
1504-00-103	ATTUNE CR Cemented Femoral Size 3 Left
1504-00-123	ATTUNE CR Cemented Femoral Size 3 Narrow Left
1504-00-104	ATTUNE CR Cemented Femoral Size 4 Left
1504-00-124	ATTUNE CR Cemented Femoral Size 4 Narrow Left
1504-00-105	ATTUNE CR Cemented Femoral Size 5 Left
1504-00-125	ATTUNE CR Cemented Femoral Size 5 Narrow Left
1504-00-106	ATTUNE CR Cemented Femoral Size 6 Left
1504-00-126	ATTUNE CR Cemented Femoral Size 6 Narrow Left
1504-00-107	ATTUNE CR Cemented Femoral Size 7 Left
1504-00-108	ATTUNE CR Cemented Femoral Size 8 Left
1504-00-109	ATTUNE CR Cemented Femoral Size 9 Left
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1504-00-202	ATTUNE CR Cemented Femoral Size 2 Right
1504-00-203	ATTUNE CR Cemented Femoral Size 3 Right
1504-00-223	ATTUNE CR Cemented Femoral Size 3 Narrow Right
1504-00-204	ATTUNE CR Cemented Femoral Size 4 Right
1504-00-224	ATTUNE CR Cemented Femoral Size 4 Narrow Right
1504-00-205	ATTUNE CR Cemented Femoral Size 5 Right
1504-00-225	ATTUNE CR Cemented Femoral Size 5 Narrow Right
1504-00-206	ATTUNE CR Cemented Femoral Size 6 Right
1504-00-226	ATTUNE CR Cemented Femoral Size 6 Narrow Right
1504-00-207	ATTUNE CR Cemented Femoral Size 7 Right
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1504-00-209	ATTUNE CR Cemented Femoral Size 9 Right
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1504-10-123	ATTUNE PS Cemented Femoral Size 3 Narrow Left
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1504-10-124	ATTUNE PS Cemented Femoral Size 4 Narrow Left
1504-10-105	ATTUNE PS Cemented Femoral Size 5 Left
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1504-10-106	ATTUNE PS Cemented Femoral Size 6 Left
1504-10-126	ATTUNE PS Cemented Femoral Size 6 Narrow Left
1504-10-107	ATTUNE PS Cemented Femoral Size 7 Left

Product Code	Description
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1504-10-223	ATTUNE PS Cemented Femoral Size 3 Narrow Right
1504-10-204	ATTUNE PS Cemented Femoral Size 4 Right
1504-10-224	ATTUNE PS Cemented Femoral Size 4 Narrow Right
1504-10-205	ATTUNE PS Cemented Femoral Size 5 Right
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Product Code	Description
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Product Code	Description
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1516-40-912	ATTUNE PS FB Insert Size 9 12 mm
1516-40-914	ATTUNE PS FB Insert Size 9 14 mm
1516-40-916	ATTUNE PS FB Insert Size 9 16 mm
1516-40-918	ATTUNE PS FB Insert Size 9 18 mm
1516-40-920	ATTUNE PS FB Insert Size 9 20 mm
1516-41-005	ATTUNE PS FB Insert Size 10 5 mm
1516-41-006	ATTUNE PS FB Insert Size 10 6 mm
1516-41-007	ATTUNE PS FB Insert Size 10 7 mm
1516-41-008	ATTUNE PS FB Insert Size 10 8 mm
1516-41-010	ATTUNE PS FB Insert Size 10 10 mm
1516-41-012	ATTUNE PS FB Insert Size 10 12 mm
1516-41-014	ATTUNE PS FB Insert Size 10 14 mm
1516-41-016	ATTUNE PS FB Insert Size 10 16 mm
1516-41-018	ATTUNE PS FB Insert Size 10 18 mm
1516-41-020	ATTUNE PS FB Insert Size 10 20 mm
1506-00-001	ATTUNE FB Cemented Tibial Base Size 1

Product Code	Description
1506-00-002	ATTUNE FB Cemented Tibial Base Size 2
1506-00-003	ATTUNE FB Cemented Tibial Base Size 3
1506-00-004	ATTUNE FB Cemented Tibial Base Size 4
1506-00-005	ATTUNE FB Cemented Tibial Base Size 5
1506-00-006	ATTUNE FB Cemented Tibial Base Size 6
1506-00-007	ATTUNE FB Cemented Tibial Base Size 7
1506-00-008	ATTUNE FB Cemented Tibial Base Size 8
1506-00-009	ATTUNE FB Cemented Tibial Base Size 9
1506-00-010	ATTUNE FB Cemented Tibial Base Size 10
1506-70-001	ATTUNE FB Cemented Tibial Base Size 1
1506-70-002	ATTUNE FB Cemented Tibial Base Size 2
1506-70-003	ATTUNE FB Cemented Tibial Base Size 3
1506-70-004	ATTUNE FB Cemented Tibial Base Size 4
1506-70-005	ATTUNE FB Cemented Tibial Base Size 5
1506-70-006	ATTUNE FB Cemented Tibial Base Size 6
1506-70-007	ATTUNE FB Cemented Tibial Base Size 7
1506-70-008	ATTUNE FB Cemented Tibial Base Size 8
1506-70-009	ATTUNE FB Cemented Tibial Base Size 9
1506-70-010	ATTUNE FB Cemented Tibial Base Size 10
1518-20-029	ATTUNE Medialized Dome Patella Size 29
1518-20-032	ATTUNE Medialized Dome Patella Size 32
1518-20-035	ATTUNE Medialized Dome Patella Size 35
1518-20-038	ATTUNE Medialized Dome Patella Size 38
1518-20-041	ATTUNE Medialized Dome Patella Size 41
1518-10-029	ATTUNE Medialized Anatomic Patella Size 29
1518-10-032	ATTUNE Medialized Anatomic Patella Size 32
1518-10-035	ATTUNE Medialized Anatomic Patella Size 35
1518-10-038	ATTUNE Medialized Anatomic Patella Size 38
1518-10-041	ATTUNE Medialized Anatomic Patella Size 41
150611001	ATTUNE RP TIB BASE SZ 1 POR
150611002	ATTUNE RP TIB BASE SZ 2 POR
150611003	ATTUNE RP TIB BASE SZ 3 POR
150611004	ATTUNE RP TIB BASE SZ 4 POR
150611005	ATTUNE RP TIB BASE SZ 5 POR
150611006	ATTUNE RP TIB BASE SZ 6 POR
150611007	ATTUNE RP TIB BASE SZ 7 POR
150611008	ATTUNE RP TIB BASE SZ 8 POR
150611009	ATTUNE RP TIB BASE SZ 9 POR
150611010	ATTUNE RP TIB BASE SZ 10 POR
150680001	S+ ATTUNE Cemented Tibial Base, RP Sz1
150680002	S+ ATTUNE Cemented Tibial Base, RP Sz2
150680003	S+ ATTUNE Cemented Tibial Base, RP Sz3

Product Code	Description
150680004	S+ ATTUNE Cemented Tibial Base, RP Sz4
150680005	S+ ATTUNE Cemented Tibial Base, RP Sz5
150680006	S+ ATTUNE Cemented Tibial Base, RP Sz6
150680007	S+ ATTUNE Cemented Tibial Base, RP Sz7
150680008	S+ ATTUNE Cemented Tibial Base, RP Sz8
150680009	S+ ATTUNE Cemented Tibial Base, RP Sz9
150680010	S+ ATTUNE Cemented Tibial Base, RP Sz10
150610001	ATTUNE TIBIAL BASE RP SZ1 CEMENTED
150610002	ATTUNE TIBIAL BASE RP SZ2 CEMENTED
150610003	ATTUNE TIBIAL BASE RP SZ3 CEMENTED
150610004	ATTUNE TIBIAL BASE RP SZ4 CEMENTED
150610005	ATTUNE TIBIAL BASE RP SZ5 CEMENTED
150610006	ATTUNE TIBIAL BASE RP SZ6 CEMENTED
150610007	ATTUNE TIBIAL BASE RP SZ7 CEMENTED
150610008	ATTUNE TIBIAL BASE RP SZ8 CEMENTED
150610009	ATTUNE TIBIAL BASE RP SZ9 CEMENTED
150610010	ATTUNE TIBIAL BASE RP SZ10 CEMENTED
151630105	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 5MM AOX
151630106	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 6MM AOX
151630107	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 7MM AOX
151630108	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 8MM AOX
151630110	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 10MM AOX
151630112	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 12MM AOX
151630114	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 14MM AOX
151630116	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 16MM AOX
151630118	ATTUNE TIBIAL INSERT RP CR INSERT SZ1 18MM AOX
151630205	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 5MM AOX
151630206	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 6MM AOX
151630207	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 7MM AOX
151630208	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 8MM AOX
151630210	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 10MM AOX
151630212	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 12MM AOX
151630214	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 14MM AOX
151630216	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 16MM AOX
151630218	ATTUNE TIBIAL INSERT RP CR INSERT SZ2 18MM AOX
151630305	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 5MM AOX
151630306	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 6MM AOX
151630307	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 7MM AOX
151630308	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 8MM AOX
151630310	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 10MM AOX
151630312	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 12MM AOX
151630314	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 14MM AOX

Product Code	Description
151630316	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 16MM AOX
151630318	ATTUNE TIBIAL INSERT RP CR INSERT SZ3 18MM AOX
151630405	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 5MM AOX
151630406	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 6MM AOX
151630407	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 7MM AOX
151630408	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 8MM AOX
151630410	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 10MM AOX
151630412	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 12MM AOX
151630414	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 14MM AOX
151630416	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 16MM AOX
151630418	ATTUNE TIBIAL INSERT RP CR INSERT SZ4 18MM AOX
151630505	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 5MM AOX
151630506	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 6MM AOX
151630507	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 7MM AOX
151630508	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 8MM AOX
151630510	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 10MM AOX
151630512	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 12MM AOX
151630514	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 14MM AOX
151630516	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 16MM AOX
151630518	ATTUNE TIBIAL INSERT RP CR INSERT SZ5 18MM AOX
151630605	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 5MM AOX
151630606	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 6MM AOX
151630607	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 7MM AOX
151630608	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 8MM AOX
151630610	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 10MM AOX
151630612	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 12MM AOX
151630614	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 14MM AOX
151630616	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 16MM AOX
151630618	ATTUNE TIBIAL INSERT RP CR INSERT SZ6 18MM AOX
151630705	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 5MM AOX
151630706	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 6MM AOX
151630707	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 7MM AOX
151630708	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 8MM AOX
151630710	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 10MM AOX
151630712	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 12MM AOX
151630714	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 14MM AOX
151630716	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 16MM AOX
151630718	ATTUNE TIBIAL INSERT RP CR INSERT SZ7 18MM AOX
151630805	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 5MM AOX
151630806	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 6MM AOX
151630807	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 7MM AOX
151630808	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 8MM AOX

Product Code	Description
151630810	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 10MM AOX
151630812	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 12MM AOX
151630814	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 14MM AOX
151630816	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 16MM AOX
151630818	ATTUNE TIBIAL INSERT RP CR INSERT SZ8 18MM AOX
151630905	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 5MM AOX
151630906	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 6MM AOX
151630907	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 7MM AOX
151630908	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 8MM AOX
151630910	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 10MM AOX
151630912	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 12MM AOX
151630914	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 14MM AOX
151630916	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 16MM AOX
151630918	ATTUNE TIBIAL INSERT RP CR INSERT SZ9 18MM AOX
151631005	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 5MM AOX
151631006	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 6MM AOX
151631007	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 7MM AOX
151631008	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 8MM AOX
151631010	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 10MM AOX
151631012	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 12MM AOX
151631014	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 14MM AOX
151631016	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 16MM AOX
151631018	ATTUNE TIBIAL INSERT RP CR INSERT SZ10 18MM AOX

Product Code	Description

Product Code	Description
151650105	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 5MM AOX
151650106	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 6MM AOX
151650107	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 7MM AOX
151650108	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 8MM AOX
151650109	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 9MM AOX
151650110	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 10MM AOX
151650112	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 12MM AOX
151650114	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 14MM AOX
151650116	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 16MM AOX
151650118	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 18MM AOX
151650120	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 20MM AOX
151650122	ATTUNE TIBIAL INSERT RP PS INSERT SZ1 22MM AOX
151650205	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 5MM AOX

Product Code	Description
151650206	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 6MM AOX
151650207	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 7MM AOX
151650208	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 8MM AOX
151650209	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 9MM AOX
151650210	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 10MM AOX
151650212	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 12MM AOX
151650214	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 14MM AOX
151650216	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 16MM AOX
151650218	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 18MM AOX
151650220	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 20MM AOX
151650222	ATTUNE TIBIAL INSERT RP PS INSERT SZ2 22MM AOX
151650305	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 5MM AOX
151650306	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 6MM AOX
151650307	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 7MM AOX
151650308	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 8MM AOX
151650309	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 9MM AOX
151650310	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 10MM AOX
151650312	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 12MM AOX
151650314	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 14MM AOX
151650316	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 16MM AOX
151650318	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 18MM AOX
151650320	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 20MM AOX
151650322	ATTUNE TIBIAL INSERT RP PS INSERT SZ3 22MM AOX
151650405	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 5MM AOX
151650406	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 6MM AOX
151650407	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 7MM AOX
151650408	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 8MM AOX
151650409	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 9MM AOX
151650410	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 10MM AOX
151650412	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 12MM AOX
151650414	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 14MM AOX
151650416	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 16MM AOX
151650418	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 18MM AOX
151650420	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 20MM AOX
151650422	ATTUNE TIBIAL INSERT RP PS INSERT SZ4 22MM AOX
151650505	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 5MM AOX
151650506	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 6MM AOX
151650507	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 7MM AOX
151650508	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 8MM AOX
151650509	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 9MM AOX
151650510	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 10MM AOX
151650512	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 12MM AOX

Product Code	Description
151650514	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 14MM AOX
151650516	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 16MM AOX
151650518	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 18MM AOX
151650520	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 20MM AOX
151650522	ATTUNE TIBIAL INSERT RP PS INSERT SZ5 22MM AOX
151650605	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 5MM AOX
151650606	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 6MM AOX
151650607	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 7MM AOX
151650608	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 8MM AOX
151650609	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 9MM AOX
151650610	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 10MM AOX
151650612	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 12MM AOX
151650614	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 14MM AOX
151650616	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 16MM AOX
151650618	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 18MM AOX
151650620	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 20MM AOX
151650622	ATTUNE TIBIAL INSERT RP PS INSERT SZ6 22MM AOX
151650705	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 5MM AOX
151650706	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 6MM AOX
151650707	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 7MM AOX
151650708	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 8MM AOX
151650709	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 9MM AOX
151650710	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 10MM AOX
151650712	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 12MM AOX
151650714	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 14MM AOX
151650716	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 16MM AOX
151650718	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 18MM AOX
151650720	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 20MM AOX
151650722	ATTUNE TIBIAL INSERT RP PS INSERT SZ7 22MM AOX
151650805	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 5MM AOX
151650806	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 6MM AOX
151650807	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 7MM AOX
151650808	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 8MM AOX
151650809	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 9MM AOX
151650810	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 10MM AOX
151650812	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 12MM AOX
151650814	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 14MM AOX
151650816	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 16MM AOX
151650818	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 18MM AOX
151650820	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 20MM AOX
151650822	ATTUNE TIBIAL INSERT RP PS INSERT SZ8 22MM AOX
151650905	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 5MM AOX

Product Code	Description
151650906	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 6MM AOX
151650907	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 7MM AOX
151650908	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 8MM AOX
151650909	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 9MM AOX
151650910	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 10MM AOX
151650912	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 12MM AOX
151650914	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 14MM AOX
151650916	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 16MM AOX
151650918	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 18MM AOX
151650920	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 20MM AOX
151650922	ATTUNE TIBIAL INSERT RP PS INSERT SZ9 22MM AOX
151651005	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 5MM AOX
151651006	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 6MM AOX
151651007	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 7MM AOX
151651008	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 8MM AOX
151651009	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 9MM AOX
151651010	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 10MM AOX
151651012	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 12MM AOX
151651014	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 14MM AOX
151651016	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 16MM AOX
151651018	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 18MM AOX
151651020	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 20MM AOX
151651022	ATTUNE TIBIAL INSERT RP PS INSERT SZ10 22MM AOX

Product Code	Description

Product Code	**Description**

Product Code	Description