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Orthopaedics

Triathlon® PKR Outcomes Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center study of the outcomes of the Triathlon® Partial Knee Resurfacing (PKR) Unicondylar Knee System

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Study Product: *Triathlon® PKR System*

Protocol Number: *66*

IDE Number: *N/A*

Version 2.0

Date: 26-Sep-2019

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Protocol Change History

Version	Description	Changed By
Version 1.1 – 6-18-08	Inclusion/Exclusion modified; addition of KOOS	Theresa D'Errico
Version 1.2 – 12-4-08	Added an AP standing film to be obtained preoperatively and at 6 weeks – all applicable sections in protocol updated – consent form also updated; added Veronica Lewis as Study Manager	Theresa D'Errico
Version 2.0 – 8-29-2019	**General:** This amendment was initiated due to the slow enrollment rate and not reaching the enrollment goal of 184 subjects. • Under the previous protocol v.1.2, 184 subjects were to be enrolled prospectively. • Under protocol v.2.0, the prospective enrollment will be closed at 80 subjects and a retrospective enrollment phase will be initiated to supplement the 80 cases in the prospective cohort. Potential subjects will be identified, screened and consented. **Study Synopsis:** Revised the methodology, study centers, enrollment goal, objectives, additional data collection and number of subjects. The evaluation schedule was revised to note that the x-rays will be optional in the retrospective cohort. **Section 2.1.1 and 2.2.2:** The primary and secondary objectives were revised. **Section- Other Data Collected:** The radiographic outcomes section was revised to note that radiographs in the retrospective arm of the study will be optional. **Section 3.1**: Amended the study enrollment study design. Prospective subject enrollment will close, and retrospective enrollment will be initiated in this amendment. Subjects that have received the study device prior to study enrollment or after the original enrollment goal was met at the study sites will be screened for inclusion in this retrospective arm of the study. **Section 3.2:** Number of centers revised. **Section 3.3:** Number of subjects revised. **Section 3.4:** Estimated study duration updated. **Section 3.5:** Enrollment goal/rate revised. **Section 4.1:** Revised inclusion criteria #6 to increase the preoperative mechanical alignment from 10 degrees varus or valgus to 15 degrees varus or valgus. **Section 7.1:** Evaluation section revised to include the process for retrospective evaluation. **Section 7.3:** Annual Follow-up visits for the subjects in the original protocol will remain unchanged, however the visit schedule for the retrospective cohort will be at 5, 7 and 10-years postoperative. **Section 9.1.1, 9.1.2, 9.1.3, 9.1.4, 9.1.5**: The statistical plan was revised including primary and secondary objectives and sample size calculation. **Section 9.4.1**: Sample size justification was revised. **Section 10.1**: Subject recruitment and screening was revised to include the addition of the retrospective cohort. **Section 15.3**: Addition of the potential for subject stipend to return for the 5-year and 10-year postoperative visit.	Lorie Gardner

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List of Abbreviations

AE	Adverse Event
AP	Anteroposterior
AVN	Avascular Necrosis
BMI	Body Mass Index
CAD	Computer Assisted Design
CSM	Clinical Study Manager
DCF	Data Clarification Form
EDC	Electronic Data Capture
FEA	Finite Element Analysis
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
KSS	Knee Society Score
KOOS	Knee and Osteoarthritis Outcome Score
M/L	Medio/Lateral
ML	Mediolateral
OA	Osteoarthritis
PCL	Posterior Cruciate Ligament
PER	Product Experience Report
PI	Primary Investigator
QOL	Quality of Life
ROM	Range of Motion
SC	Study Coordinator
SF-12	Short-Form 12
TA	Traumatic Arthritis
UHMWPE	Ultra High Molecular Weight Polyethylene
UKA	Unicompartmental Knee Arthroplasty

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Study Synopsis

Title	The Triathlon® PKR Unicondylar Knee System Outcomes Study
Short Title	**Triathlon® PKR Study**
Protocol Number	66
Phase	Post-marketing
Methodology	This study is a prospective, post-market, multi-center evaluation of the Triathlon® PKR unicondylar knee system with an additional retrospective enrolled and prospectively followed cohort of cases.
Study Duration	10-year follow-up for each case
Study Center(s)	A minimum of four centers will participate.
Objectives	**Primary:** The 10-year mean KSS Function Score is comparable to the Triathlon CR KSS Function Score at 10-years. **Secondary:** A 10-year Kaplan Meier survival analysis will be presented including only prospective cases.
Additional Data Collection	To compare OR time, hospital stay, blood loss, return to ROM, KSS, activity level, adverse event rates, and radiographic data to UKA.
Reference Therapy	Triathlon CR Stryker Sponsored Study; Clinical Trials NCT 00966979; Survivorship data from national registries will supplement the study survivorship data.
Number of Subjects	A total of 175 cases (knees) will be enrolled. There are 80 cases enrolled from the prospective cohort and a planned minimum 95 cases is the goal from the retrospective cohort.

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Diagnosis and Main Inclusion Criteria	**Inclusion Criteria** 1) The subject is a male or non-pregnant female 21-75 years of age at the time of enrollment. 2) The subject requires a primary cemented unicompartmental knee replacement. 3) The subject has a diagnosis of osteoarthritis (OA) or post-traumatic arthritis (TA). 4) The subject has clinically intact cruciate and collateral ligaments and no ligamentous instability is present. 5) The subject has less than 10 degrees of flexion contracture and greater than 90 degrees of flexion. 6) The subject's preoperative mechanical alignment is less than or equal to 15 degrees of varus and 15 degrees of valgus. 7) The subject has signed the IRB approved study specific Informed Patient Consent Form. 8) The subject is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation. **Exclusion Criteria** 1) The subject has inflammatory arthritis or avascular necrosis (AVN). 2) The subject is obese, BMI > 35. 3) The subject has a history of total or unicompartmental (contralateral compartment and/or patellofemoral joint) reconstruction of the affected joint. 4) The subject has a history of ACL reconstruction. 5) The subject has had a high distal femoral, or proximal tibial osteotomy. 6) The subject has a mental, neuromuscular or neurosensory disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care and/or limit the ability to assess the performance of the device. 7) The subject has a systemic or metabolic disorder leading to progressive bone deterioration that the surgeon feels would affect the overall outcome of the study. 8) The subject is immunologically suppressed or is receiving chronic steroids (>30 days duration). 9) The subject has a known sensitivity to device materials. 10) The subject's bone stock is compromised by disease and/or infection which cannot provide adequate support and/or fixation to the prosthesis. 11) The subject's bone stock is compromised by a prior implantation which cannot provide adequate support and/or fixation to the prosthesis.

	12) The subject has an active or suspected latent infection in or about the knee joint. 13) The subject is a prisoner.
Study Device	Triathlon® PKR Unicondylar Knee System consisting of three main components: • Triathlon® PKR femoral component • Triathlon® PKR tibial tray component • Triathlon® PKR tibial insert component
Statistical Methodology	**Primary Hypothesis:** The mean KSS Function score is non-inferior to 84 points with a margin of 6 points. (Ha: u - 84>-6). The reference value 84 is from the Triathlon CR 10-year KSS Function value. The reference value of 6 is the minimal clinically important difference (MCID) per reference. **Secondary Hypotheses:** The 90% confidence interval of the success rate will be computed at 10-year post-surgery. For the non-inferiority comparison, the lower bound of this 90% confidence interval will be compared with 80%. For the superiority comparison, the lower bound of this 90% confidence interval will be compared with 88%.

Evaluation Schedule

CASE REPORT FORMS										
EVALUATION	***HISTORY / PREOP (-3 mnths)***	***INTRA-OP***	***2 WKS (± 1 wk)***	***6 WKS (± 1 wk)***	***3 Months (± 2 wks)***	***1YR. (± 2 mos)***	***2 YRS. (± 2 mos)***	***5 YRS. (± 3 mos)***	***7 YRS. (± 3 mos)***	***10 YRS. (±3 mos)***
Inclusion/ Exclusion	X									
Demographics /Medical History	X									
Surgical Details		X								
PRE Operative Evaluation/KSS	X									
POST Operative Evaluation/KSS			X	X	X	X	X	X	X	X
SF-12	X		X	X	X	X	X	X	X	X
Activity Questionnaire	X		X	X	X	X	X	X	X	X
LEAS	X		X	X	X	X	X	X	X	X
KOOS	X		X	X	X	X	X	X	X	X
RADIOGRAPHS**										
	PREOP (-1 year)	***INTRA-OP***	***2 WKS (± 1 wk)***	***6 WKS (± 1 wk)***	***3 Months (± 2 wks)***	***1YR. (± 2 mos)***	***2 YRS. (± 2 mos)***	***5 YRS. (± 3 mos)***	***7 YRS. (± 3 mos***	***10 YRS. (±3 mos)***
AP long standing	X			X						
AP standard	X			X		X	X	X	X	X
ML standard	X			X		X	X	X	X	X
Merchant/ skyline	X			X		X	X	X	X	X

*Cases enrolled in the retrospective cohort will have preoperative, postoperative and one postoperative baseline visit (either 2 wks., 6 wks. or 3 months) documented from the medical records. The earliest prospective visit is 5-years postoperative, therefore, the earliest surgical date for this retrospective cohort is 2015.

**For the retrospective study cohort, the x-rays will be optional.

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1 Introduction

This document is a protocol for a human research study. This study will be conducted in compliance with the protocol, Good Clinical Practice Standards, associated Federal regulations, and all applicable research requirements.

1.1 Background

Unicompartmental knee arthroplasty was introduced approximately 30 years ago. Since its introduction there have been changes and advances to this area of orthopaedics. Implant designs, new materials, surgical technique and patient selection have improved[1]. In addition, UKA has regained popularity due to recent reports of implants survivorship being similar to TKA[2]. It has been suggested in the literature that UKA offers advantages as compared with TKA: the procedure is less invasive, patients tend to achieve a better range of motion, and patients report a more "normal feeling" joint[3]. Naal et al. continued to state that knee kinematics in UKA are more like the normal knee because of the preservation of both cruciate ligaments.

Due to the higher success of UKA systems being established, focus has shifted to other areas surrounding this system/procedure. These other areas include, but are not limited to: smaller incision surgery, less blood loss, quicker return to function. Because of this shift in focus, data will be collected around these areas to show how the Triathlon® PKR compares to data reported in the literature.

The Triathlon® Partial Knee Resurfacing (PKR) system addresses an unmet need in the market for a resurfacing system that utilizes the most current technology available. As the popularity of the unicompartmental procedure increases[4], the expectation for better outcomes is also anticipated to increase. Triathlon® Partial Knee Resurfacing was designed not only to provide a system that matches today's expectations for survivorship, but also to provide the functionality required by today's more demanding patients. The Triathlon® Partial Knee Resurfacing provides surgeons with the appropriate solution for patients with isolated unicompartmental osteoarthritis.

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This new resurfacing system provides surgeons with the ability to remove a small amount of bone on the affected compartment of the knee while saving the healthy compartments of the knee as well as the cruciate ligaments. The system utilizes special instruments designed to simplify the technical aspects of the procedure while providing the capability to accommodate minimally invasive surgery (MIS) and navigation procedures. A simplified two-step gap balancing system has been incorporated that provides an elegant solution for balancing flexion and extension gaps. For the patient, Stryker's patented single radius design has been incorporated that has already been shown to improve mid flexion stability and functional performance in our total knee systems. Stryker's proprietary X3 highly cross-linked bearing technology is utilized in the Triathlon PKR system. X3 Advanced Bearing Technology has demonstrated up to 96% decrease in wear in laboratory testing compared to competitive premium bearing surfaces in total knee replacements[5]. Triathlon is the only unicompartmental knee with this technology.

1.2 Study Device

The Triathlon® PKR Unicompartmental System has been developed as the platform for the Early Intervention (EI) product portfolio for Stryker Orthopaedics. The Triathlon® PKR unicompartmental Knee System consists of three primary components including a femoral component fabricated from cast cobalt-chromium-molybdenum alloy, a tibial tray fabricated from cast cobalt-chrome-molybdenum alloy, and a tibial insert fabricated from ultra-high molecular weight X3® UHMWPE. The Triathlon® PKR femoral component was designed with the same philosophy and rationale as the Triathlon® Total Knee System to have a single radius to recreate the natural movement of the epicondyle and to promote deep flexion. The underside of the tibial component contains a cement recess, a round peg and an angled peg for cement fixation and to provide stability. The inside of the tray has tabs and lip for locking the tibial insert in place.

1.3 Preclinical Data

Performance Testing - Bench:

The Triathlon® PKR components are substantially equivalent to other unicompartmental knee systems regarding design and materials. Testing was conducted to compare the subject components to its predicates. Examples of predicate knee systems distributed by Howmedica Osteonics are: the EIUS® Unicompartmental Knee System (K992287 & K033769), the SCR® Unicompartmental Knee Prosthesis (K896856 & K911373), the UNIX™ Unicompartmental Knee

System (K923011) and the Triathlon® Knee System (K031729, K040267) and X3® UHMWPE Tibial Inserts (K051146, K063423, K070095, K072221, K141056.

Tibial baseplate fatigue testing, range of motion and constraint, contact area/stress analysis, and component interlock strength of the locking mechanism testing were performed. Engineering analyses were conducted on the fatigue strength of the femoral component and implant fixation as well.

Tibial Baseplate Fatigue Testing

Fatigue testing was conducted to determine the fatigue strength of the subject tibial baseplate under repetitive physiologic loading. Testing was based on ASTM F1800-04, with the following deviations: Loading magnitude and location are representative of a normal level walking activity with a polyurethane foam baseplate support block representing the bone density of the tibial plateau. The largest size tibial tray was tested to represent worst case because it has the largest unsupported area yielding the highest bending stress. The thinnest size 6 insert was used, because it is also worst case since it would transfer the highest concentrated load to the baseplate.

Five constructs were loaded at 1610N (362 lbs.) for 10M cycles. All constructs were able to withstand 10M without failure without any cracks or fractures detected under fluoro-penetrant inspection meeting the acceptance criteria. (Report Number: RD-7-063)

UHMWPE Tibial Bearing Components

The minimum thickness of the thinnest tibial insert under the condyle meets the 6mm minimum noted by an FDA guidance document therefore testing of this component was not necessary.

Range of Motion/ Constraint Analysis

The Triathlon® PKR Knee is a prosthesis which relies on the restoration of the normal length and tension to the ligamentous structures for stability. Range of motion is both controlled and limited by soft tissue structures around the knee. Since the tibial insert is designed as a spacer device, it provides limited constraint during the range of motion in flexion or extension. The device mimics the kinematics of a normal knee because the natural ligaments and muscles need to provide the constraint for this device. An engineering analysis was conducted to assess the range of motion up to 135˚ of flexion and the contact area/contact stress was evaluated up to 135˚ of flexion. Both

the Range of Motion and Range of Constraint analysis reveal that the Triathlon® PKR system is similar to the EIUS predicate device. The results are consistent with other predicate unicondylar knees. Also, since the Triathlon® PKR tibial insert design is based on the EIUS articulating surface, it will have the same range of constraint. (Technical Memo to DHF 10823 dated 6-28-07)

Contact Area/Stress Analysis

The purpose of this test was to compare tibio-femoral contact area/contact stress of the Triathlon® Tibial Insert to the EIUS tibial insert, since this predicate was used in the design of the articulating surface of the subject device. Finite element analysis (FEA) tools were used to characterize the overall stress state of both tibial inserts in this comparative study. This type of analysis provides an excellent technique for comparing the different tibial inserts, as it considers not only the contact area and contact stress, but also maximum principal and von Mises stresses. This study demonstrated the contact stress state of the Triathlon® PKR system is equal to or less than the EIUS unicompartmental size XS assembly. (Report Number: RD-07-067)

To verify if the FEA was an acceptable means of comparing the subject and predicate devices, testing was conducted to compare the EIUS FEA results to mechanical testing with Tekscan at the same flexion angles. Both methodologies showed an increase in the stress with an increase in flexion angle with the FEA yielding higher results while the FEA underestimated the contact area when compared to the Tekscan results. The comparison concludes the FEA is an acceptable methodology to predicate contact area and contact stress. (Report Number: RD-07-066)

Tibial Insert/Tibial Tray Locking Strength Testing

In order to test the locking mechanism of the Triathlon® PKR System, a distraction test was conducted to determine the load required to push out the tibial insert from the tibial tray. The inserts were sterilized by gas plasma and are also representative of the N2Vac inserts since the ultimate strength of the two materials is equivalent. Both the smallest and largest sizes of the system were tested to cover the range of sizes to be offered. The size 6 is considered the worst case since it is the largest size and would see the highest forces. All components failed by the shearing of the anterior locking barbs on the insert, which is the same failure mode as the predicate, SCR insert and tray. The results were compared to the Size 11 SCR insert/tray construct tested under the same conditions. Because the size 6 would see the highest loads, it is acceptable for the Size 1 and Size 6 to be considered equivalent to the largest SCR construct

(Size 11). The analysis concluded that the two systems are statistically equivalent. (Report Number: RD-07-064)

Femoral Fatigue Analysis

An engineering analysis was conducted comparing the strength of the subject femoral component to a predicate, the UNIX femoral component. The analysis concluded that the UNIX femoral component had about 1.2 times higher stresses than the subject device. Based on these results, the Triathlon® PKR components are, at a minimum, equivalent to the predicate device regarding femoral fatigue strength. (Technical Memo to DHF 10823 dated 1-22-08)

Implant Fixation Analysis

The largest and smallest sizes of the subject device were compared to the predicate SCR baseplate and UNIX femoral component for implant fixation. The Triathlon® PKR components have a larger surface area than the predicate components. Therefore, the fixation at the bone-cement interface is equivalent. (Technical Memo to DHF 10823 dated 7-5-07)

Conclusion

Based upon the described mechanical testing, the Triathlon® PKR System is substantially equivalent to other predicate knees for its intended use, material and design.

1.4 Clinical Data to Date

This study is the first Stryker sponsored multi-center prospective data collection on the Triathlon® PKR Unicompartmental knee system.

2 Study Objectives

2.1 Efficacy

2.1.1 Primary

The 10-year mean KSS Function Score is comparable to 84 points (the mean of the Triathlon CR KSS Function Score at 10-years postoperatively). The mean PKR 10-year score is calculated from both the prospective and retrospective cases.

2.1.2 Secondary

A 10-year Kaplan Meier survival analysis will be presented at the end of the study using only the prospective cases, to prevent bias. Survivorship data from the national registries below will be presented along with the study survivorship data.

- Australian Orthopaedic Association National Joint Replacement Registry
- National Joint Registry for England, Wales, Northern Ireland and the Isle of Man
- The New Zealand Joint Registry
- Swedish Knee Arthroplasty Register

Other Data Collected

Surgical Details

The Surgical Details form will record information related to the surgery, such as: duration of surgery, estimated blood loss, and if an intraoperative complication has occurred. Please See Appendix II for a sample Surgical Details Form.

Clinical Outcome

Clinical Outcomes will be evaluated via the total Knee Society Score, including pain and function, pre-operatively, and at the 2-week, 6-week, 3-month, 1, 2, 5, 7- and 10-year visits.

Patient Outcomes

SF-12: General health and well-being will be collected via the SF-12 form at all preoperative and postoperative intervals.

Activity Scales: Three activity assessments will be conducted at each visit. First, the patient will complete the Lower Extremity Activity Scale (LEAS). This questionnaire asks the patient to select one of the options that best describes their physical function at that point in time. The second Activity Questionnaire consists of open-ended entries where the patient can note the recreational/sport activities they are participating in at that point in time. The third questionnaire for the patient to complete is the Knee and Osteoarthritis Outcome Score (KOOS): This score was developed as an instrument to assess the patient's opinion about their knee and associated problems

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Radiographic Outcomes

Radiographs will be optional in this retrospective arm of the study. If taken at the annual visit, an anteroposterior, medial-lateral, and merchant or skyline view will be collected. Although preoperative AP long-standing film will not be collected, it is required to ensure that the patient did not have a deformity of more than 15 degrees of varus/valgus preoperatively during the screening process.

Radiographs will be evaluated by an independent reviewer. Parameters for radiographic failures will follow the guidelines that have been set by the Knee Society but will be modified due to the patella not being replaced. Radiolucencies are determined by measuring the width of the radiolucent lines for each of the zones in millimeters for both components. Radiolucency in at least 50% of a zone and measuring at least 1mm in width is defined as radiolucency present. A migrating or shifting prosthesis with or without the disappearance of radiolucent lines should be considered as a possible or impending failure regardless of the score.

Subsidence is defined as settling of the prosthetic component in bone and is related to the distance between fixed bony landmarks on the tibia and the prosthesis. Note: Knee Society guidelines state that direct subsidence without angular movement cannot be detected because there is no reference point.

2.2 Safety

Reported protocol defined adverse events will be compared to literature. It is expected that the adverse event rates reported for the Triathlon® PKR Unicompartmental Knee System will be comparable to those reported in the literature.

3 Clinical Study Plan

3.1 Study Design

A prospective, post-market, multi-center design will be employed in the first phase. Prospective enrollment closed early due to lack of enrollment and a retrospective arm is initiated to enroll additional cases. Prospective data will be obtained on the retrospective cases to 10-years.

3.2 Number of Centers

There have been 80 cases enrolled to date in the prospective arm of the study at seven study centers. The number of centers will be determined by the number of cases that are screened successfully into the retrospective cohort of this amendment.

3.3 Number of Subjects

Prospective enrollment will close with this protocol amendment at 80 cases. The last case was enrolled on January 29, 2018. Retrospective enrollment will be initiated at current study centers who have subjects that meet the enrollment criteria. The number of subjects obtained retrospectively will be a minimum of 95 cases from those implanted by the surgeon prior to the initiation of this study and any cases done after the original enrollment goal was met. If there are insufficient cases at the existing sites, other sites will be considered. These cases will have the Triathlon® PKR Unicompartmental Knee System. A total of 175 cases (knees) will be enrolled, 80 cases from the prospective cohort and a planned minimum of 95 cases from the retrospective cohort.

3.4 Estimated Study Duration

The enrollment period for the retrospective arm is estimated at six months to identify, screen and enroll all the retrospective cases, once IRB approval has been granted. All cases will be followed through 10 years postoperative.

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4 Eligibility

The following criteria will be used to distinguish subjects eligible for enrollment into this study.

4.1 *Inclusion Criteria*

1) The subject is a male or non-pregnant female 21-75 years of age at the time of enrollment.
2) The subject requires a primary cemented unicompartmental knee replacement.
3) The subject has a diagnosis of osteoarthritis (OA) or post-traumatic arthritis (TA).
4) The subject has clinically intact cruciate and collateral ligaments and no ligamentous instability is present.
5) The subject has less than 10 degrees of flexion contracture and greater than 90 degrees of flexion.
6) The subject's preoperative mechanical alignment is less than 15 degrees of varus and 15 degrees of valgus.
7) The subject has signed the IRB approved study specific Informed Patient Consent Form.
8) The subject is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

4.2 *Exclusion Criteria*

1) The subject has inflammatory arthritis or avascular necrosis (AVN).
2) The subject is obese, BMI >35.
3) The subject has a history of total or unicompartmental (contralateral compartment and/or patellofemoral joint) reconstruction of the affected joint.
4) The subject has a history of ACL reconstruction.
5) The subject has had a high distal femoral, or proximal tibial osteotomy.
6) The subject has a mental, neuromuscular or neurosensory disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care and/or limit the ability to assess the performance of the device.

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7) The subject has a systemic or metabolic disorder leading to progressive bone deterioration that the surgeon feels would affect the overall outcome of the study.
8) The subject is immunologically suppressed or is receiving chronic steroids (>30 days duration).
9) The subject has a known sensitivity to device materials.
10) The subject's bone stock is compromised by disease and/or infection which cannot provide adequate support and/or fixation to the prosthesis.
11) The subject's bone stock is compromised by a prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
12) The subject has an active or suspected latent infection in or about the knee joint.
13) The subject is a prisoner.

5 Subject Enrollment

5.1 Treatment Assignment

All subjects enrolled in this study will have the Triathlon® PKR Unicompartmental Knee System. See **Appendix A** for Component Listing.

5.2 Randomization

This study will enroll under a non-randomized study design.

6 Device Description

6.1 Study Device

The Triathlon® Partial Knee Resurfacing (PKR) System has been cleared for use in the U.S. and is therefore considered a post market assessment under 510(k) clearance number K071881. See **Appendix B** for the FDA clearance letters. The Triathlon® PKR System consists of the following three primary components listed with this 510(k)clearance number: Triathlon® PKR Femoral Component (K071881), Triathlon® PKR Tibial Insert (K071881) and Triathlon® PKR Tibial Tray

(K071881). The Triathlon® PKR (Partial Knee Resurfacing) System consists of sterile, single-use components intended for replacement of the femorotibial regions of the knee joint either on the lateral or medial side. The system includes a femoral component and a modular tibial tray with a mating tibial insert. The system is intended for cemented fixation. The articular surface of the Triathlon® PKR insert is designed to allow the following kinematics: Range of Motion 0° hyperextension to 135° flexion.

The Triathlon® PKR (Partial Knee Resurfacing) System labeling can be found in **Appendix C.**

FEMORAL COMPONENT:

The Triathlon® PKR femoral component was designed with the same philosophy and rationale as the Triathlon® Total Knee System to have a single radius to recreate the natural movement of the epicondyle and to promote deep flexion. It is available in sizes ranging from Size 1 to Size 6 in right lateral/left medial and left lateral/right medial configurations. The component is fabricated from cast CoCrMo alloy and has two fixation pegs. The bone/cement facing surface of the component is grit blasted and the articulating surface is highly polished.

The Triathlon® PKR femoral component included in this protocol is:

- 5610-F-xxx

TIBIAL TRAY:

The Triathlon® PKR tibial component is cast cobalt chromium alloy. There are six sizes (1, 2, 3, 4, 5, and 6) in left medial/right lateral and right medial/left lateral configurations. The underside of the tibial component contains a cement recess, a round peg and an angled peg for cement fixation and to provide stability. The inside of the tray has tabs and lip for locking the tibial insert in place. The surface finish of the underside of baseplate is grit blasted and the topside is bead blasted.

The Triathlon® PKR tibial tray included in this protocol is:

- 5620-B-xxx

TIBIAL INSERT:

The tibial insert is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE) and is available in six sizes with thicknesses of 8mm, 9mm, 10mm and 12mm for the left medial/right

lateral and right medial/left lateral compartments. The articulating surface of the insert is based on the EIUS tibial insert cleared in K992287 and K033769. The locking mechanism between the insert and the tibial tray is based on the SCR® tibial insert design cleared in 510(k) K896856 and K911373. The tibial insert has undercuts on the bottom. When the insert slides under the lip on the tray, it snap-fits into place and the metal tabs on the tray mechanically lock the insert in place via the undercuts on the bottom of the insert. The minimum thickness of the thinnest tibial insert under the bearing surface meets the 6mm minimum noted by FDA guidance.

X3® polyethylene is a highly cross-linked polyethylene manufactured through a proprietary process where the polyethylene receives 30 kiloGrays of gamma radiation, which generates free radicals and cross-linking in UHMWPE prior to machining. The polyethylene is then annealed below melting point to promote cross-linking and maintains mechanical strength[1], crystallinity[2], and density[3]. This also stabilizes the free radicals[4]. This process is repeated twice.
The Triathlon® PKR tibial insert included in this protocol is:

- 5630-G-xxx

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1 X3 UHMWPE maintains mechanical properties for Tensile Yield Strength and Ultimate Tensile Strength of N_2Vac gamma sterilized UHMWPE as measured by ASTM D638. Tensile Yield Strength was 23.2 ± 0.4 MPa and 23.5 ± 0.3 MPa for N_2Vac UHMWPE and X3 UHMWPE, respectively. Ultimate Tensile Strength was 54.8 ± 2.5 MPa and 56.7 ± 2.1 MPa for N_2Vac UHMWPE and X3 UHMWPE, respectively.
2 X3 UHMWPE has similar crystalline and lamellar structure as N_2Vac gamma sterilized UHMWPE as measured by Small Angle X-ray Scattering (SAXS) and Differential Scanning Calorimetry (DSC) analysis. DSC determined crystallinity was 61.3 ± 0.8% and 61.7 ± 0.6% for N_2Vac UHMWPE and X3 UHMWPE, respectively. Lamellar crystal thickness was 23.0 and 23.6 nanometers for N_2Vac UHMWPE and X3 UHMWPE, respectively.
3 X3 UHMWPE increases crosslink density over N_2Vac gamma sterilized UHMWPE by 87% as measured by swell ratio per ASTM F2214. Crosslink density as measured by swell ratio was 0.08 ± 0.00 mol/dl and 0.15 ± 0.01 mol/dl for N_2Vac UHMWPE and X3 UHMWPE, respectively.
4 X3 UHMWPE virtually eliminates free radicals, as measured by Electron Spin Resonance (ESR). A very low (noise level, near instrument detection limit) concentration of residual free radicals was detected in the X-3 UHMWPE. A 99% reduction of free radicals ($14 \pm 2 \times 10^{14}$ spins/gram versus $1550 \pm 32 \times 10^{14}$ spins/gram) was found when compared to N_2Vac gamma sterilized UHMWPE.

6.2 Device Retrieval Process

Stryker Orthopaedics will retrieve any Triathlon® PKR System components and/or adjacent tissues for analysis to help characterize potential device-related complications. In the event that any portion of the Triathlon® PKR system is removed from a study subject, please follow the procedure outlined below.

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1. When revision of a study subject is scheduled, the study coordinator (SC) should complete a Product Experience Report (PER) and contact the CSM as soon as possible.
2. After contacting the CSM, the SC will fax the PER to the clinical study manager (CSM).
3. The CSM will obtain a PER number and relay the number to the SC.
4. The CSM will send an Exakt-Pak with corresponding PER label to the Field Representative for the site.
5. The field representative will retrieve the device, place it in the Exakt-Pak with the corresponding label and send to the CSM.
6. The CSM will then take the retrieval to Product Surveillance for analysis.
7. A summary of results will be provided to the investigator upon his/her request.

7 Evaluations

7.1 Initial Retrospective Evaluation

Once the subject has been screened and confirmed that they meet all inclusion and exclusion criteria, the subject will be consented. A medical record review will commence to obtain baseline information. The subject will be scheduled for the next annual follow-up that they are due for based on the original surgery date and as per the Evaluation Schedule on page 4. The earliest visit accepted will be five years postoperative, which means subjects will have to have a surgery date of 2015 or earlier. The initial medical record review will include obtaining: demographic/medical history, surgical details, a baseline evaluation at either two weeks, six weeks or three months and Knee Society Score elements; pain level and range of motion values. The anteroposterior (AP, standard and long-standing), mediolateral and merchant/skyline x-rays are optional. The AP long-standing film will only be used as a reference to determine if the subject meets the protocol inclusion of not having a preoperative varus or valgus deformity of greater than 15 degrees.

For the initial retrospective cases, as much of the preoperative data and baseline data will be retrospectively collected from the medical records upon completion of written consent. The patient reported outcomes (SF-12, LEAS, Activity Questionnaire and KOOS) will not be available prior to consent but will be collected from the point of consent forward to ten years.

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7.2 Surgery

Surgical details will be collected from the operative notes and at the time of surgery. For the retrospective arm of the study, as much of the surgical details data will be collected from the operative notes and medical records. Information collected on the surgical details includes items such as: type of anesthesia, surgical approach, incision length, navigation use, bone removal, soft tissue released, ACL status, component catalog and serial number, blood loss, duration of surgery, and Outerbridge Classification.

Because this is a unicompartmental knee system, it is important to gauge the degree of disease in the contralateral compartment and patellofemoral compartment of the knee at the time a unicondylar knee replacement is being considered. Therefore, the Outerbridge Classification[6] will be used in this study to assess the contralateral compartment and patellofemoral compartment in the knee joint. This classification system uses a grading system from Grade 0 to Grade IV to indicate the quality of the cartilage in each portion of the knee joint.

The Outerbridge Classification is as follows:

Grade 0: Normal cartilage
Grade I: Cartilage with softening and swelling
Grade II: fragmentation and fissuring in an area half an inch or less in diameter
Grade III: fragmentation and fissuring in an area more than half an inch in diameter
Grade IV: Erosion of cartilage down to bone

7.3 Annual Follow up Visits

Prospective cases will follow the original protocol for the postoperative visits. The retrospective cases enrolled under this amendment will be evaluated at 5, 7, and 10 years postoperatively, depending on the surgical date at the time of enrollment. At each office visit the following evaluations will be collected: Knee Society Score, SF-12, LEAS, Activity Questionnaire, KOOS. The anteroposterior (standard), mediolateral and merchant/skyline x-rays are optional.

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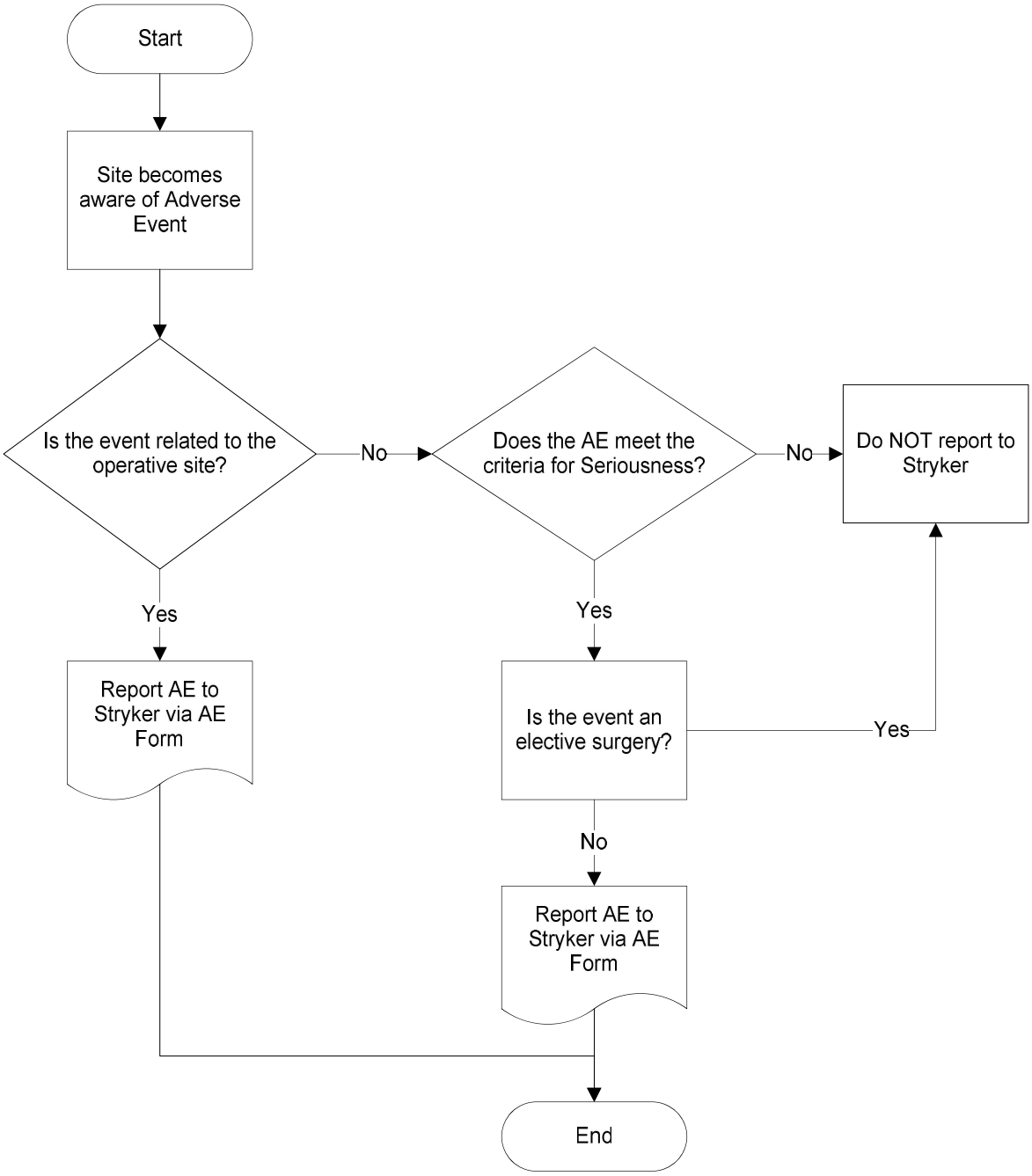
8 Adverse Events

8.1 Adverse Event (AE) Reporting Requirements for this study

- All adverse events that meet the definition of serious (not to include elective surgeries)
- All AE's related to operative site, regardless of seriousness

See Adverse Event Decision Tree – Figure 1


Start
Site becomes aware of Adverse Event
Is the event related to the operative site?
No
Does the AE meet the criteria for Seriousness?
No
Do NOT report to Stryker
Yes
Yes
Report AE to Stryker via AE Form
Is the event an elective surgery?
Yes
No
Report AE to Stryker via AE Form
End

Adverse Event Reporting Period

The study period during which adverse events must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. In other words, the start of study procedures is considered to be the point of consent. Therefore, any adverse events which fit the protocol defined reportable events must be reported from the time of obtaining consent throughout the study duration.

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on protocol defined adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedure results should be recorded in the source document, though they should be grouped under one diagnosis. The clinical course of each event should be followed until resolution or until it is determined at the end of the study that the adverse event will not resolve.

During the medical record review of the retrospectively enrolled cases, any operative site adverse events will be documented as per the usual procedure. For prospective follow-up, these cases will adhere to the adverse event reporting described above.

General Physical Examination Findings

At screening for inclusion into the study, any clinically significant abnormality should be recorded as a preexisting condition. During the study, any new clinically significant findings/abnormalities that meet the definition of a protocol defined adverse event must also be recorded and documented as an adverse event.

8.2 General Adverse Event Definitions

Following is a list of definitions related to adverse events.

Adverse Event

An ***adverse event*** (AE) is any untoward medical occurrence in a clinical investigation subject, which changes the medical baseline of the subject. An adverse event can be an unfavorable and unintended sign, symptom or disease, whether or not related to the study device (AEs may also

be referred to as complications). In this study only adverse events that are either serious or related to the operative site are to be reported (see Figure 1).

Anticipated Adverse Event

An ***anticipated adverse event*** is an AE, of which the nature, severity or degree of incidence is known and identified in applicable product labeling, published literature or study protocol. The list of events which are anticipated are provided in the Risk/Benefit Assessment (section #12).

Adverse Device Effect

An ***adverse device effect*** (ADE) is a negative change in the subject's health that may have been caused by or associated with the use of the device.

Serious Adverse Event

A serious adverse event (SAE) meets one or more of the following definitions:

- Resulted in in-patient hospitalization
- Resulted in prolonged existing hospitalization
- Resulted in persistent or significant disability/incapacity
- Resulted in permanent impairment of a body function or permanent damage to a body structure
- Necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure
- Was a life-threatening situation
- Resulted in patient death

Unanticipated Adverse Device Effect

An ***unanticipated adverse device effect*** (UADE) is any serious adverse effect on health, safety or any life-threatening problem or death caused by, or associated with a device, if that effect, a problem or death not previously identified in nature, severity or degree of incidence, or any other unanticipated serious problem associated with a device and related to the rights, safety or welfare of subjects.

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8.3 Study Sponsor Notification by Investigator

The sponsor requests that certain events be faxed to us for timely notification. Those that need to be submitted to the sponsor are:

- Events which are serious as per the definition of SAE.
- Events which are deemed to be "related to" or "uncertain" in regard to relation to the device.

A copy of the completed Adverse Event (AE) form must be completed by the investigator and sent to the study sponsor within 24 hours. The investigator will keep a copy of this AE form on file at the study site and submit the hard copy as per case report form data submission procedures. Report noted events to:

Lorie Gardner Phone: (201) 831-5491 lorie.gardner@stryker.com

At the time of the initial report, the following information should be provided:

- Subject Number
- A description of the event
- Date of onset
- Current Status
- Whether the study treatment was discontinued
- The Investigator's assessment of the association between the event and study treatment

8.3.1 EC/IRB Notification by Investigator

Reports of adverse events (including follow-up information) must be submitted to the IRB according to their specific requirements. Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's binder.

8.4 Medical Monitoring

It is the responsibility of the Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above. The Sponsor will conduct formal investigations via the Product Surveillance

Department of those adverse events which are submitted through our Produce Experience Report System.

9 Statistical Plan

9.1 Efficacy

9.1.1 Primary Efficacy Parameters

The primary efficacy parameter is the mean 10-year KSS Function Score combining the prospective and retrospective cases.

9.1.2 Secondary Efficacy Parameters

The secondary efficacy parameter is revision or removal of any component.

9.1.3 Primary Efficacy Hypothesis

The null hypothesis: H_0, the mean 10-year KSS function (u) is inferior to 84 points with a margin of 6 points. The alternative hypothesis to be tested is, H_a, the mean 10- year KSS function is non-inferior to 84 points with a margin of 6 points.

H_0: $u-84 < -6$

H_a: $u-84 \geq -6$

9.1.4 Primary Efficacy Analysis

A 90% 2-sided confidence interval of the mean 10-year KSS function will be computed. If the lower bound of the confidence interval is greater than 78 then the non-inferiority hypothesis will be supported. If the lower bound of the confidence interval is above 84, then the superiority will be supported

9.1.5 Secondary Efficacy Analysis

The Kaplan-Meier survival curve of revision or removal of any component will be displayed at the end of the study using SAS/PROC LIFETEST. Two survival curves will be displayed, one for prospectively enrolled cases only, one for both prospectively enrolled cases and retrospectively enrolled cases. And the 10-year survival rate and 95% Confidence Interval will be presented as well.

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For the Additional Data Collection when data is available, descriptive statistics (e.g., mean, percentage) and 95% confidence interval will be presented.

The descriptive statistics (e.g., mean, minimum, maximum, standard deviation) of length of OR time, hospital stay, and amount of blood loss will be presented.

A change of the KSS scores, ROM, LEAS, KOOS, Activity Questionnaire activity levels, and SF-12 scores at each post-surgery visit from pre-surgery will be summarized. The descriptive statistics (e.g., mean, standard deviation) will be presented, where applicable. In addition, a p-value will be presented to determine of the change from pre-surgery is non-zero, if appropriate.

Radiographic data will be summarized in table format.

9.2 Safety

9.2.1 Safety Parameters

Safety parameters include all protocol defined adverse events reported.

9.2.2 Safety Analysis

All adverse events will be listed, tabulated, and summarized by event, number, and percent of cases/patients. Adverse event rates and exact 95% confidence intervals will be presented.

9.3 Missing Data

No missing data will be imputed for the primary analysis and secondary analyses.

Missing data for the KOOS will be treated in agreement with the SF-36, substituting missing values with the average value for the dimension. If more than two items were omitted, the response will be considered invalid.

9.4 Statistical Methodology

9.4.1 Data Summary

Descriptive statistics will be computed for all baseline conditions and demographic parameters. If appropriate, the data will be presented by appropriate subgroups (e.g., center). In general, follow-up data will be summarized according to visit. For parameters

represented by continuous variables (e.g., blood loss, KSS), the summaries will consist of the mean, median, standard deviation, minimum, and maximum values. For categorical variables (e.g., revision), the number and percent in each category will be presented. Ninety percent confidence intervals will be presented where tests of non-inferiority will be performed, otherwise the 95% confidence interval will be presented. Descriptive statistics and statistical comparisons for important demographic, efficacy, and safety variables will be provided in tables.

Statistical analyses utilizing SAS® software version 9.1 or higher will be used.

Sample Size Justification

The Stryker sponsored Triathlon CR study has a mean 10-year KSS function 84 points and a standard deviation of 21, A literature review shows the minimal clinically important difference for KSS function is 6 points[60], with a 5% type I error rate and a power of 80%, the sample size is 76. By factoring in a 20% attrition rate at 10 years postoperatively, the adjusted sample size will be 95 cases.

9.4.2 Interim Analyses and early Stopping Considerations

No interim analysis is planned.

9.4.3 Efficacy Patient Populations

Per Protocol Population:

All subjects other than those censored who received the Triathlon® PKR Unicondylar Knee System. Data for patients where a protocol deviation occurred which could affect patient outcome will not be included.

The primary and secondary efficacy analyses will be based on the per protocol population.

9.4.4 Safety Patient Population

Safety Population

The safety population will include all non-censored subjects who received the Triathlon® PKR Unicondylar Knee System.

9.4.5 Censored Cases

Data for patients where a protocol deviation occurred which could affect patient outcome will be censored from the Efficacy and Safety Patient Populations. They will be reported on separately.

If a case receives a unicompartmental knee arthroplasty in the contralateral compartment of the study knee, this case will be considered a deviation and censored from analysis for all areas except survivorship. This case will be included in the survivorship analysis only.

10 Study Procedures

10.1 Subject Recruitment and Screening

Patients will be recruited at the study sites by a review of medical records for prior cases receiving the Triathlon PKR unicompartmental device. Once a patient is identified as having a PKR unicompartmental device implanted outside of the initial prospective study, it will be determined if they are deceased or had the device revised, which would exclude them during the screening process. Once a patient is identified as a potential study candidate, the study coordinator will review all the inclusion and exclusion criteria to ensure the patient meets those criteria. If that screening is successful, the study coordinator will contact the patient to conduct a telephone screening to review the study details and inquire as to the level of interest to participate. If there is interest, it will be determined if the patient has the capacity to give informed consent, and if so, a verbal informed consent will be provided. A signature will be obtained on the formal approved informed consent document to complete the enrollment into study.

10.2 Patient Informed Consent and Guidelines

All subjects for this study will be provided a consent form describing the study and providing sufficient information for subjects to make an informed decision about their participation in this study. The informed consent must contain all elements required by the FDA under 21 CFR part 50; in addition to any other elements required by state, local and institutional policies. See Appendix D for a sample Subject Informed Consent Form. This consent form will be submitted with the protocol for review and approval by the IRB for the study. All subjects must provide

written consent after having had adequate time to consider their participation in the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any protocol related procedures that are not part of the subject's normal care. Written documentation of consent must be provided on the consent's signature page in addition to a note in the patient medical records indicating the date that consent was obtained. The investigator-designated research professional obtaining the consent must also sign this consent form. The subject or their legal representative should receive a signed copy of the consent according to Good Clinical Practice (GCP) guidelines.

The procedure for obtaining informed consent is outlined below:

- Use a current IRB approved copy of the consent form.
- Review the consent thoroughly with the patient before having him/her sign.
- After the patient has consented to the procedures, ensure he/she sign and date the consent form.
- The person obtaining consent also signs and dates the signature page.
- Provide a copy of the consent to the patient.
- If required, provide the hospital with a copy of the signed consent.
- Maintain the signed original in the patient's study chart.

10.3 Early Withdrawal of Subjects

When and How to Withdraw Subjects

In the event that the subject is discontinued by the investigative site after discussion with the sponsor prior to the final study evaluation, the subject is notified that they are no longer in the study and a Study Termination CRF will be completed. The following is a list of reasons for which subjects may be terminated, and the date of termination that should be used on the Study Termination CRF in each situation. This list is not all inclusive:

Termination Reason	**Date of Termination**
Death	Date of death
Investigative site termination	Date of study close-out visit
Lost to follow-up	Date Stryker termination approval given
Voluntary withdrawal	Date subject notified site of withdrawal

Termination Reason	Date of Termination
Revision/removal of study device	Date of revision/removal procedure
Study device not implanted	Date of surgery
Surgery not performed	Date Stryker termination approval given

If the subject fails to return for their follow-up appointments, every effort should be made to contact the subject to assess his/her health status. If after attempting to contact the subject through three documented phone calls and a certified letter, the subject still does not respond, he/she will be considered lost to follow-up. A Study Termination CRF will be completed **only after notifying Stryker of the subject's status** and **being given approval to terminate**.

Study Completion

When a subject completes the study according to protocol, including the final study evaluation, a Study Termination CRF will be completed and the termination date will be the date of the subject's last evaluation.

11 Data Management

11.1 Database

Data will be collected at each site and sent to the Sponsor for entry into a database which will reside at the sponsor site. It is possible that at least one site may record data via an electronic data entry capture (EDC) system. Patient data will be collected, processed, and monitored according to the protocol schedule by the sponsor or sponsor representatives. Sample case report forms are provided in **Appendix E.**

11.2 Confidentiality

This study will comply with the 2002 privacy rule of the Health Insurance Portability and Accountability Act (HIPAA). As such, the Sponsor will obtain an authorization to receive personal healthcare information as part of the informed consent process. In addition, the sponsor will only collect that information which is necessary to support the objectives of the clinical trial and will take precautions to ensure that data received is as de-identified as possible. In the case that some identified information is received, the Sponsor will ensure that any identifying information will not be reported. Study subjects will authorize the Sponsor to use their health information in

support of the clinical trial during the Informed Consent Process. Should a subject choose to withdraw authorization, the Sponsor may use data collected prior to the withdrawal of authorization in order to maintain data integrity.

11.3 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

All data points collected during follow-up visits must be documented in the patient chart. This includes range of motion values, pain and function as well as complications and additional comments. The Informed Consent process should also be documented in the patient chart. Monitors will be comparing the case report forms against the source documents for accuracy. The monitor will seek to draw a reference between each data point on the CRF and the patient chart. Thus, one cannot derive pain, range of motion or function based on a chart note that reads "Patient doing well." Every effort should be made to ensure complete source documentation.

11.4 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

For specific instructions on CRF completion, please consult the Guide to Case Report Forms. Case report forms should be completed, signed by the investigator, and returned to the sponsor

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within two weeks of the patient evaluation date. If errors or omissions are noted by the sponsor upon receipt of the forms, a data clarification form (DCF) will be sent to the site for clarification. Completed DCFs should be returned to the sponsor within two weeks of receipt.

11.5 Protocol Deviations

Any deviation from this protocol categorized as a 'Major Protocol Deviation' will be recorded by the Sponsor and must be reported to the investigational center's overseeing IRB according to their reporting procedures. Major protocol deviations for this study may include the following; this list may not be all-inclusive:

- Informed consent deviations, including but not limited to:
    - Study procedures performed prior to informed consent
    - Incorrect informed consent version used
- Patient enrolled does not meet the inclusion/exclusion criteria
- Protocol specified study component(s) not implanted
- Off label component usage

If the center anticipates a possible protocol deviation, the investigator or SC should contact Stryker for guidance.

11.6 Records Retention

It is the investigator's responsibility to retain study essential documents for two years after the date of the final report. These documents should be retained for a longer period if required by an agreement with the sponsor.

12 Risk / Benefit Assessment

12.1 *Risk Category*

There are no additional risks associated with participating in this study.

12.2 Potential Risk

The study involves the routine assessment of a knee arthroplasty procedure. The device under study has been cleared for marketing by the FDA and will be used according to its labeling. Assessment involves questionnaires, patient and physician assessments, and routine x-rays. The

information collected will be kept confidential and will comply with the Health Insurance Portability and Accountability Act (HIPAA).

While the expected life of knee replacement components is difficult to estimate, it is finite. Adverse effects associated with standard unicompartmental knee arthroplasty include the following:

These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads normal to healthy bone.

Dislocation of the prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.

Serious complications may be associated with any total joint replacement surgery. These complications include but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.

Wear of polyethylene components has occurred and literature reports[7] have associated its occurrence with bone resorption, loosening and infection.

Metal sensitivity reactions have been reported following joint replacement.

Adverse effects may necessitate reoperations, revision, arthrodesis of the involved joint, and/or amputation of the limb.

With all implant devices, asymptomatic, localized progression bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third-body wear.

Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

12.3 *Expected Complications and Rates of Occurrences*

The safety objective will compare the Triathlon® PKR rates to the literature rates at 10 years. Percentages for UKA have been taken from published literature and represent averages or ranges as noted.

Table I

Unicompartmental Knee Arthroplasty Adverse Event Literature Summary

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	Rate	Mean follow-up
Related to Surgery			
Femoral fracture intra-op	72 kns	1 event - 1%[8]	40.2 months
Tibial fracture /intra-op	72 kns	3 events - 4%[8]	40.2 months
Patellar fracture		Not available	

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	Rate	Mean follow-up
/intra-op			
Supracondylar fracture/intra-op		Not available	
Superficial wound infection	88 cases/79 pts 212 kns	2 event - 2%[9] 1 event - 1%[10]	9 years unknown
Deep joint infection	79 kns/69 pts 56 kns/56 pts 212 kns 514 kns 203 kns/174 pts 2288 kns 318 kns/270 pts	2 events - 2.7%[11] 1 event - 2%[1] 2 events - 1 %[10] 1 event - 1 %[10] 2 events - 1%[12] 5 events - <1%[13] 1 event - <1%[14]	3.35 years (40.2 mnths) 2 years unknown 2-year follow-up 14.8 years 10-year follow-up 8 months
Wound related (non-infected)	88 cases/79 pts 212 kns	1 instance - 1%[9] 1 event - 1 %[10]	9 years unknown
Peroneal nerve palsy		Not available	
Other operative	62 kns/51 pts 62 kns/51 pts 41 kns/41 pts 26 kns/17 pts 26 kns/17 pts 30 kns/28 pts 30 kns/28 pts 56 kns/56 pts 56 kns/56 pts 212 kns 212 kns 212 kns	2 MCL avulsions - 3%[15] 1 MCL avulsion - 2%Error! Bookmark not defined. 1 MCL fracture - 2%[16] 1 hemarthrosis - 4%[17] 1 arthrolysis - 3%[18] 1 mobilization - 3%[18] 2 events to remove loose bodies - 4%[1] Clicking sensation - 2%[1] 9 cement fragments - 4%[10] 3 partial lat menisectomies-1%[10] 1 femoral trochlea chondroplasty-1%[10] 1 osteochondral loose body removal - 1%[10]	7.5 years 12 years 2 years 6.9 years 6.9 years 7-10-year follow-up 7-10-year follow-up 2 years 2 years unknown unknown unknown
Related to Implant			
Prosthesis fracture/femoral component	88 cases/79 pts 203 kns/174 pts	4 events - 5%[9] 2 events - 1%[12]	9 years 14.8 years
Prosthesis fracture/tibial component	30 kns/28 pts	1 event - 3%[18]	7-10 year follow-up
Prosthesis fracture/tibial insert	30 kns/28 pts 75 kns/62 pts	1 event - 3%[18] 17 events - 23%[19]	7-10-year follow-up 18 months
Prosthesis fracture/patellar component		Not available	

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	**Rate**	**Mean follow-up**
Femoral component loosening	88 cases/79 pts 20 kns/17 pts 123 kns/121 pts 26 kns/17 pts 30 kns/28 pts 221 knees 39 kns/36 pts 2288 kns	1 event - 1% 1 event - 6%[20] 2 events - 2%[21] 6 events - 23%[17] 1 event - 3%[18] 6 events - 3 %[10] 15 events - 38%[22] 38 events - 2%[Error! Bookmark not defined.]	9 years 4-8 years follow-up out to 2 years 6.9 years 7-10 years unknown not stated - retrospective 10 years
Tibial component loosening*	88 cases/79 pts 79 knees/69 pts 42 kns/45 kns 20 kns/17 pts 123 kns/121 pts 136 kns/103 pts 26 kns/24 pts 30 kns/28 pts 56 kns/56 pts 212 kns 203 kns/174 pts 245 kns 2288 kns 318 kns/270 pts 161 kns/158 pts	5 events - 6%[9] 6 events - 8.2%[11] 1 event - 2%[23] 1 event - 6%[20] 4 events - 3%[21] 8 events - 6%[24] 2 events - 9%[25] 4 events - 13%[18] 1 event - 2%[1] 5 events - 3%[10] 4 events - 2%[12] 19 events - 8%[26] 44 events - 2%[Error! Bookmark not defined.] 3 events - 1%[14] 5 events - 2%[27]	9 years 3.35 years (40.2 mnths) 2 years 4-8 years F/Up done out to 2 years minimum 21-year follow-up minimum 21-year follow-up 7-10-year follow-up 2 years Unknown 14.8 years 9 year mean 10 years 8 months 5-14-year follow-up
Tibial subsidence	140 kns/103 pts	6 events - 5%[28]	15-year minimum follow-up
Patellar component loosening		Not Available	
Patellar component dislocation		Not Available	
Patellar subluxation		Not Available	
Tibial component dislocation	2288 kns	21 events - 1%[Error! Bookmark not defined.] [dislocation & instability combined]	Unknown

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	**Rate**	**Mean follow-up**
Revision (femoral component)	88 cases/79 pts 59 kns/48 pts 62 kns/51 pts 62 kns/51 pts 41 kns/41 pts 516 kns/427 pts 45 kns/42 pts 20 kns/17 pts 136 kns/103 pts 38 kns/28 pts 140 kns/103 pts 30 kns/28 pts 212 kns 203 kns/174 pts 38 kns/29 pts	19 events - 21%[9] 2 events- 3%[29] 1 event- 2%[15] 2 events - 4%[Error! Bookmark not defined.] 1 event - 2%[16] 36 events - 7%[30] 2 events - 4%[23] 1 event - 6%[20] 17 events - 13%[24] 1 event - 3%[31] 12 events - 9%[28] 6 events - 20%[18] 9 events - 4.25%[10] 12 events - 6%[12] 1 event - 3%[31]	9 years 13 years 7.5 years 12 years 2 years 10 years 4-8 years minimum 21-year follow-up 4 years 15-year minimum 7-10 year minimum unknown 14.8 years mean 4 years
Revision (tibial component)*	88 cases/79 pts 59 kns/48 pts 62 kns/51 pts 62 kns/51 pts 41 kns/41 pts 516 kns/427 pts 45 kns/42 pts 20 kns/17 pts 136 kns/103 pts 38 kns/28 pts 28 kns/24 pts 140 kns/103 pts 30 kns/28 pts 212 kns 203 kns/174 pts 38 kns/28 pts	19 events - 21%[9] 2 events- 3%[29] 1 event - 2%[15] 2 events - 4%[Error! Bookmark not defined.] 1 event - 2%[16] 36 events - 7%[30] 2 events - -4%[23] 1 event - 6%[20] 19 events - 14%[24] 1 event - 3%[31] 13 events - 50%[32] 14 events - 10%[28] 6 events - 20%[18] 9 events - 4.25%[10] 12 events - 6%[12] 1 event - 3%[31]	9 years 13 years 7.5 years 12 years 2 years 10 years 2 years 4-8 years minimum 21-year follow-up 4 years minimum 12-year follow-up 15 year minimum 7-10 years follow-up Unknown 14.8 years mean 4 years
Revision (patellar component)		Not Available	
Revision (tibial insert)	59 kns/48 pts 62 kns/51 pts 62 kns/51 pts 516 kns/427 pts 45 kns/42 pts 38 kns/28 pts 30 ks/28 pts 38 kns/28 pts	2 events - 3%[29] 1 event - 2%[15] 2 events - 4%[Error! Bookmark not defined.] 36 events - 7%[30] 2 events - 4%[23] 1 event - 3%[31] 6 events - 20%[18] 1 event - 3%[31]	13 years 7.5 years 12 year 10 years 2 years 4 years 7-10 years follow-up mean 4 years
Early failure due to irradiated poly	514 kns	24 events - 5 %[10]	2-year follow-up

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	**Rate**	**Mean follow-up**
Inability to obtain bony ingrowth - cementless	514 kns	3 events - 1%[10]	2-year follow-up
Wear of polyethylene	203 kns/174 pts 245 kns 2288 kns 38 kns/28 pts 75 kns/62 pts 516 kns427 pts 26 kns/17 pts	3 events - 2%[12] 43 events - 16%[26] 19 events - 1%[Error! Bookmark not defined.] 1 event - 3%[31] 28 events - 37%[19] 8 events - 2%[30] 6 events - 23%[17]	14.8 years 9 years mean 10-year follow-up mean 4 years 18 months 10 years mean 6.9 years
Narrowing of lateral tibio-femoral compartment	245 knees	2 events - 1%[26]	9 year mean
Other			
Revision due to progression of arthritis	88 cases/79 pts 79 kns/69 pts 59 kns/48 pts 62 kns/51 pts 62 kns/51 pts 516 kns/427 pts 181 kns/117pts 136 kns/103 pts 26 kns/24 pts 140 kns/103 pts 1819 kns 203 kns/174 pts 161 kns/158 pts	9 events - 10%[9] 1 event - 1.4%[11] 2 events - 3%[29] 1 event - 2%[15] 2 events - 4%[Error! Bookmark not defined.] 20 events - 4%[30] 1 event - .5%[21] 9 events - 7%[24] 7 events - 30%[32] 7 events - 5.1%[28] 77 events - 4 %[33] 7 events - 3%[12] 1 event - 1%[27]	9 years 3.35 years (40.2 mnths) 13 years 7.5 yrs 12 years 10 years 3 years minimum 21-year follow-up minimum 12 years follow-up 15 year minimum 10 years 14.8 years 5-14-year follow-up
Progression of arthritis in the involved compartment	26 kns/24 pts	4 events - 17%[32]	minimum 12 years follow-up
Instability	161 kns/158 pts	1 event[27]	5-14-year follow-up
Supracondylar Femoral fracture/post-op		Not Available	
Tibial fracture post-op	123 kns/121 pts	2 events - 2%[21]	(avg not stated) F/Up out to 2 years
Tibial plateau fracture	79 kns/69 pts 62 kns/51 pts 62 kns/51 pts 318 kns/270 pts	3 events - 4.1%[11] 3 events - 5%[15] 3 events - 5%[Error! Bookmark not defined.] 1 event - <1%[14]	3.35 years (40.2 mnths) 7.5 years 12 years 8 months
Patellar fracture /post-op		Not Available	
Soft tissue trauma		Not Available	
Hematoma		Not Available	

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	Rate	Mean follow-up
Excessive knee pain	79 kns/69 pts 516/427pts 45 kns/42 pts 181 kns/117 pts 136 kns/103 pts 140 kns/103 pts 30 kns/28 pts 2288 kns 318 kns/270 pts 161 kns/158 pts	4 events - 5.5%[11] 1 event - .2%[30] 1 event - 2%[23] 1 event - .5%[21] 2 events - 1 %[24] 1 event - .7%[28] 1 event - 3%[18] 48 events - 2%Error! Bookmark not defined. 1 event - <1%[14] 1 event - 1%[27]	3.35 years (40.2 mnths) 10 years 2 years 3 years minimum 21-year follow-up 15-year minimum 7-10-year follow-up 10-year follow-up 8 months 5-14-year follow-up
Heterotopic Ossificans		Not Available	
Reflex Sympathetic Dystrophy		Not Available	
Arthrofibrosis		Not Available	
Pulmonary embolism		Not Available	
Thrombophlebitis		Not Available	
Carcinoma		Not Available	
Genitourinary		Not Available	
Bronchopulmonary		Not Available	
Cardiovascular	26 kns/17 pts	2 nonfatal cardiac events - 8%[17]	6.9 years
Gastrointestinal		Not Available	
Dermatological		Not Available	
Trauma (non-op side)		Not Available	
Neurosensory		Not Available	
Other systemic	38 kns/28 pts 38 kns/28 pts 26 kns/17 pts	1 case conjuctivitis - 3%[31] 2 UTI's - 5%[31] 2 UTI's - 8%[17]	4 years 4 years 6.9 years
DVT	160 kns/147 pts 88 cases/79 pts 62 kns/51 pts 26 kns/17 pts	5 events - 3%[34] 1 event - 1%[9] 2 events - 4%[15] 1 event - 4%[17]	5.5 years (66 mnths) 9 years 7.5 years 6.9 years
Myocardial Infarction		Not Available	

Event	Unicompartmental Knee Replacement PUBLISHED LITERATURE		
	N=	Rate	Mean follow-up
Death	135 kns/124 pts	29 deaths - 23%[35]	5.82 yrs. mean follow-up
	26 kns/17 pts	3 deaths - 18%[17]	6.9 yrs. mean follow-up
	26 kns/24 pts	2 deaths - 8%[32]	minimum of 12 years
	140 kns/103 pts	65 deaths - 63%[28]	15 yr. minimum follow-up
	62 kns/60 pts	5 deaths - 8%[18]	7-10 yr. follow-up
	160 kns/147 pts	7 deaths - 48%[34]	66 months (5.5 yrs.)
	59 kns/48 pts	5 deaths - 10%[29]	13 years
	62 kns/51 pts	10 deaths - 20%[15]	7.5 average
	62 kns/51 pts	13 deaths - 25%Error! Bookmark not defined.	12 year mean
	72 kns/51 pts	7 deaths - 14%[8]	40.2 months
	45 kns/42 pts	1 death - 2%[23]	2-year follow-up
	20 kns/17 pts	1 death - 6%[20]	4-8 years
	181 kns/117 pts	7 deaths - 6%[21]	3 years mean
	136 kns/103 pts	87 deaths - 84%[24]	21-year minimum

*This section includes all polyethylene components and metal tibial trays.

Since comparisons will also be made to total knee systems, Table II has also been included. This table summarizes published literature as well as current rates in our Stryker Clinical Multi-center Studies.

Table II

Total Knee Arthroplasty Adverse Event Summary

Event	Stryker Clinical Studies*	Published Literature
Related to Surgery		
Femoral fracture intra-op	0.31%	0.1% [36]
Tibial fracture/intra-op	0%	0.07[37]
Patellar fracture/intra-op	0%	0.68%[37] in revision
Supracondylar fracture/intra-op	0.06%	Not available
Superficial wound infection	1.19%	3.9%[38] (4.1 yrs mean f/u)
Deep joint infection	0.56%	1.0%[39] (6.5 yrs mean f/u)
Wound related (non-infected)	2.44%	Not available
Peroneal nerve palsy	0.19%	0.3%[40] (3.9 yrs mean f/u)
Other operative	15.88%	Not available

Event	Stryker Clinical Studies*	Published Literature
Related to Implant		
Prosthesis fracture/femoral component	0%	Not available
Prosthesis fracture/tibial component	0%	Not available
Prosthesis fracture/tibial insert	0%	Not available
Prosthesis fracture/patellar component	0%	Not available
Femoral component loosening	0%	0%[41] (5 yrs avg f/u)
Tibial component loosening	0.25%	10%[42]
Patellar component loosening	0%	3.9%[43] within first 3 years
Patellar component dislocation	0.06%	Not available
Patellar subluxation	0.25%	Not available
Tibial component subsidence	0%	Not available
Tibial component dislocation	0%	2%[44] (12 yr avg f/u)
Revision (femoral component)	0.88%	0.08%[42] (5.9 yrs avg f/u)
Revision (tibial component)	1.38%	0.23%[42] (5.9 yrs avg f/u)
Revision (patellar component)	0.25%	0.23%[42] (5.9 yrs avg f/u)
Revision (tibial insert)	2.31%	0.31%[42] (5.9 yrs avg f/u)
Other		
Supracondylar Femoral fracture/post-op	0%	0.3-2.5%[45] (3yrs avg f/u)
Tibial fracture post-op	0%	0.4%[37]
Patellar fracture/post-op	0.44%	3.8%[46] (0.68-21.0%,5 yrs avg f/u)
Soft tissue trauma	1.44%	Not available
Hematoma	1.69%	0.6%[47] (w/in first 30 days)
Excessive knee pain	3.06%	7.1%[48] (w/in 3 yrs)
Heterotopic Ossificans	0%	15.0%[49] (w/in 2 yrs of surgery)
Reflex Sympathetic Dystrophy	0.40%	0.8%[50]
Arthrofibrosis	3.00%	1.6%[51]
Pulmonary embolism	1.15%	0.9%[52], 0.8%[51], 1.5%[53] (w/in 1 yr post-op)

Event	Stryker Clinical Studies*	Published Literature
Thrombophlebitis	0.29%	Not available
Carcinoma	0.79%	Not available
Genitourinary	3.81%	0.8-35.0%[49] (w/in 2yrs)
Bronchopulmonary	2.37%	1.8%[54]
Cardiovascular	5.03%	1.0-1.5%[55] (4.3 yrs avg f/u)
Gastrointestinal	3.74%	0.06-0.7%[55] (4.3 yrs avg f/u)
Dermatological	1.72%	1.2%[54]
Trauma (non-op side)	1.58%	Not available
Neurosensory	3.02%	0.5%[54]
Other systemic	27.37%	Not available
DVT	1.29%	1.85%[53] (w/in 1 year of surgery)
Death	1.15%	0.6%[52], 0.7%[51], 7.5%[54] includes intra-op, and post-op

*Stryker Sponsored Studies used: Scorpio+MBK, Scorpio CR, Triathlon® CR and Triathlon® PS

Data from the following Stryker sponsored clinical studies was used as a basis for this table: Scorpio+ MBK, Scorpio CR, Triathlon® CR and Triathlon® PS clinical studies. There were 1,599 total cases in 1,392 patients when combining these four studies. Percentages for operative and device related events were calculated by dividing the number of cases with one or more reported event by the number of cases (knees) enrolled. Systemic event rates were calculated by dividing the number of patients with one or more reported event by the number of patients enrolled. The protocols for the Scorpio+ MBK and Triathlon® PS studies required reporting of all adverse events while the protocol for the Scorpio PS required that only operative related events be reported. The protocol for the Triathlon® CR study required that operative site events and any event meeting the definition of "serious" were reported. Percentages for TKA were taken from published literature (references listed below) represent averages or ranges as noted.

12.4 Protection Against Risks

Patients will be treated in the best medical judgment of the investigator, regardless of the study protocol. If an investigator must deviate from the written protocol to protect the health or well being of the patient, this deviation will be promptly reported to both the IRB and the study sponsor.

12.5 *Potential Benefits to the Subject*

There is no guarantee that patients will personally benefit from inclusion in this study. Patients may undergo more thorough screening and follow-up than non-study patients and may benefit from this increased surveillance. This study seeks to provide clinicians information about this system/device by comparing this treatment/device to published results for other treatments/devices. Information gathered in this study may benefit others undergoing this procedure in the future.

13 Study Monitoring, Auditing, and Inspecting

13.1 Study Monitoring Plan

Monitors are persons employed by sponsors to review the conduct of clinical studies to assure that the clinical investigators abide by their obligations to conduct clinical trials properly. Proper monitoring ensures adequate protection of the rights of human subjects, the safety of subjects involved in a clinical investigation and the quality and integrity of data submitted as a result of the investigation.

This study will be monitored at least once a year, with additional visits as necessary. The investigator will allocate adequate time for such monitoring activities. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all study-related documents and study related facilities and has adequate space to conduct the monitoring visit. The monitor will review all source documents and compare them to the data contained in the case report forms, in addition to performing a periodic review of Regulatory documents (ex. IRB approvals). The monitors will need the following when they visit:

- An area where they can review records
- Patient case books
- Patient charts pulled at the site
- Regulatory documents
- Time to meet with the study coordinator and the Investigator

13.2 Auditing and Inspecting

A quality assurance audit is a form of review that provides additional confidence to the sponsor concerning the validity and accuracy of clinical study data that may be submitted to the FDA or for publication. The purpose of investigator audits is to ensure that the investigator has maintained all study information according to the sponsor's protocol and standard operating procedures and in compliance with FDA regulations.

The investigator will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, and/or government regulatory bodies of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities.

14 Ethical Considerations

This study is to be conducted according to US standards of Good Clinical Practice and applicable government regulations including Title 21 CFR part 50 and 56 and Title 46 CFR part 160 and 164.

This protocol and any amendments will be submitted to a properly constituted independent Institutional Review Board (IRB) for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. See Appendix I for a copy of the Subject Informed Consent Form. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

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15 Study Finances

15.1 Funding Source

This study is financed by Stryker Orthopaedics.

15.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by their IRB or a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study.

15.3 Subject Stipends or Payments

Patients in the prospective arm of the study will have incentives to return for follow-up visits through a patient retention program at those sites with prior IRB approval for this program as detailed in protocol version 1.2 **See Appendix F** for details.

For the retrospectively enrolled, prospectively followed cohort, Stryker may reimburse subjects with a modest stipend of $50.00 at the 5-year and 7-year interval and $100.00 at the 10-year time interval to offset their travel costs and potential insurance costs to return to the surgeon's office for protocol-required data collection. This stipend system must be approved by the Institution's IRB prior to implementation and will be based upon individual IRB approval from each site.

Patient attrition can occur for a variety of reasons, including a patient's loss of health insurance coverage or coverage denial. In a case where a patient has lost health insurance coverage or been denied coverage and no other coverage is available, Stryker Orthopaedics may, on a case-by-case basis, reimburse investigators for office visits and radiographic charges for patients involved in this study in order to facilitate data retrieval. The physician or the office staff should contact the study manager prior to scheduling the patient to discuss this possibility and receive pre-approval. After receipt of the completed data forms, the physician must submit either evidence of coverage denial (i.e. an Explanation of Benefits form) or a letter explaining that the patient does not have insurance. Other visits, procedures, and assessments done other than

those specified in the protocol will not be reimbursed. Reimbursement may be provided under the following conditions:

- Study patients who lose insurance coverage after enrollment into the study.
- An insurance carrier refuses to pay for a follow-up visit and/or x-rays.
- An insurance carrier refuses to provide a patient referral to see the investigator for follow-up.
- Under extreme circumstances, and with prior approval, Stryker may reimburse a patient for the cost of transportation to and from the investigator's office for a protocol-required office visit.
- This policy is the same for all participating study patients, and does not bias against any particular patient or study cohort.

16 Publication Plan

It is anticipated that a publication of the multi-center study results will be compiled and submitted to a peer-reviewed journal at the time the study cohort reaches ten years of follow-up. Additional publication proposals may be made by investigators at any time and will be considered.

At the completion of the study, each participating study investigator shall have independent publication privileges for their own center's results. These manuscripts and abstracts will be delayed until after the multi-center publication is submitted. All publications of the data shall be submitted to Stryker for review prior to submission for publication. Stryker shall not edit or otherwise influence the publications other than to ensure that confidential information is not disclosed, and that the data is accurately represented. Any publications resulting from this study must be submitted to Stryker Orthopaedics for review at least 60 days prior to submission of publication.

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Appendix A

Component Listing

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Triathlon PKR Femoral Component	
Catalog no.	**Size (mm)**
5610-F-101	#1 LM/RL
5610-F-102	#1 RM/LL
5610-F-201	#2 LM/RL
5610-F-202	#2 RM/LL
5610-F-301	#3 LM/RL
5610-F-302	#3 RM/LL
5610-F-401	#4 LM/RL
5610-F-402	#4 RM/LL
5610-F-501	#5 LM/RL
5610-F-502	#5 RM/LL
5610-F-601	#6 LM/RL
5610-F-602	#6 RM/LL

Triathlon PRK Tibial Tray/Baseplate	
Catalog no.	**Size (mm)**
5620-B-101	#1 LM/RL
5620-B-102	#1 RM/LL
5620-B-201	#2 LM/RL
5620-B-202	#2 RM/LL
5620-B-301	#3 LM/RL
5620-B-302	#3 RM/LL
5620-B-401	#4 LM/RL
5620-B-402	#4 RM/LL
5620-B-501	#5 LM/RL
5620-B-502	#5 RM/LL
5620-B-601	#6 LM/RL
5620-B-602	#6 RM/LL

Triathlon PKR Tibial Insert	
Catalog no.	**Size (mm)**
5630-G-108	#1 LM/RL -8MM
5630-G-109	#1 LM/RL -9MM
5630-G-110	#1 LM/RL -10MM
5630-G-112	#1 LM/RL -12MM
5630-G-120	#1 RM/LL -10MM
5630-G-122	#1 RM/LL -12MM
5630-G-128	#1 RM/LL -8MM
5630-G-129	#1 RM/LL -9MM
5630-G-208	#2 LM/RL -8MM
5630-G-209	#2 LM/RL -9MM
5630-G-210	#2 LM/RL -10MM
5630-G-212	#2 LM/RL -12MM
5630-G-220	#2 RM/LL -10MM
5630-G-222	#2 RM/LL -12MM
5630-G-228	#2 RM/LL -8MM
5630-G-229	#2 RM/LL -9MM
5630-G-308	#3 LM/RL -8MM
5630-G-309	#3 LM/RL -9MM
5630-G-310	#3 LM/RL -10MM
5630-G-312	#3 LM/RL -12MM
5630-G-320	#3 RM/LL -10MM
5630-G-322	#3 RM/LL -12MM
5630-G-328	#3 RM/LL -8MM
5630-G-329	#3 RM/LL -9MM

Triathlon PKR Tibial Insert	
Catalog no.	**Size (mm)**
5630-G-408	#4 LM/RL -8MM
5630-G-409	#4 LM/RL -9MM
5630-G-410	#4 LM/RL -10MM
5630-G-412	#4 LM/RL -12MM
5630-G-420	#4 RM/LL -10MM
5630-G-422	#4 RM/LL -12MM
5630-G-428	#4 RM/LL -8MM
5630-G-429	#4 RM/LL -9MM
5630-G-508	#5 LM/RL -8MM
5630-G-509	#5 LM/RL -9MM
5630-G-510	#5 LM/RL -10MM
5630-G-512	#5 LM/RL -12MM
5630-G-520	#5 RM/LL -10MM
5630-G-522	#5 RM/LL -12MM
5630-G-528	#5 RM/LL -8MM
5630-G-529	#5 RM/LL -9MM
5630-G-608	#6 LM/RL -8MM
5630-G-609	#6 LM/RL -9MM
5630-G-610	#6 LM/RL -10MM
5630-G-612	#6 LM/RL -12MM
5630-G-620	#6 RM/LL -10MM
5630-G-622	#6 RM/LL -12MM
5630-G-628	#6 RM/LL -8MM
5630-G-629	#6 RM/LL -9MM

Appendix B

510 (k) Clearance Letters

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K071881

OCT - 9 2007

510(k) Summary of Safety and Effectiveness
Triathlon® Knee System Line Extension

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Vivian Kelly, Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	July 6, 2007

Device Identification

Proprietary Name:	Triathlon® PKR System
Common Name:	Knee Prosthesis Components
Classification Name and Reference:	Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained, Cemented Prosthesis, 21 CFR §888.3530
Proposed Regulatory Class:	Class II
Device Panel/Product Code:	87 HRY, Prosthesis, Knee, Femorotibial, semi-constrained, Cemented, Metal/Polymer

Description:

The Triathlon® PKR System is a modular unicondylar knee prostheses consisting of sterile, single-use components intended for replacement of the medial or lateral femoral condyle regions for either the right or left knee.

Indications for Use:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are intended for implantation with bone cement.

Substantial Equivalence:

The device is substantially equivalent to its predicates for femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analyses demonstrate that the components from these systems are compatible when used for femorotibial replacement. Examples of predicate knee systems include the Triathlon® Knee System (K031729, K040267) and X3® UHMWPE Tibial Inserts and Patellar Components (K051146 & K063423), the EIUS® Unicompartmental Knee System (K992287 & K033769), the SCR® Unicompartmental Knee Prosthesis (K896856 & K911373) and the UNIX™ Unicompartmental Knee System (K923011.) Based upon the mechanical testing, the Triathlon® PKR System is substantially equivalent for its intended use to other femorotibial replacement knees currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2007

Howmedica Osteonics Corp.
% Ms. Vivian Kelly, RAC
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

Re: K071881
Trade/Device Name: Triathlon PKR System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: July 6, 2007
Received: July 9, 2007

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071881

Device Name: Triathlon® PKR System

Indications for Use:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are intended for implantation with bone cement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071881

Appendix C

Product Labeling

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stryker
Howmedica
OSTEONICS

Triathlon® Partial Knee Resurfacing

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430 USA
A subsidiary of Stryker Corporation

Telephone #: +1 201-831-5000

CE 0086

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QIN4388 Rev. AB

Refer to product label for CE mark status and Legal Manufacturer.
The CE mark is only valid if also found on the product label.

QIN 4388, Ver. AB ECN Release Date: Apr 27, 2
Print Date: Aug 03, 2018 15:41:17 GMT

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Labeling Symbols

	Attention, See Instructions for Use
	Do not Reuse
STERILE R	Sterilized using Irradiation
STERILE GP	Sterilized using Hydrogen Peroxide
STERILE EO	Sterilized using Ethylene Oxide
	Use by Date
	Date of Manufacture
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalog Number
LOT	Batch Code
SN	Serial Number
MR	MR Safe
	MR Conditional
	MR Unsafe

QIN 4388, Ver. AB ECN Release Date: Apr 27, 2
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Triathlon Partial Knee Resurfacing 1
Resurfaçage de genou partiel Triathlon 7
Triathlon Oberflächenersatz für Knieteilprothesen 13
Rivestimento parziale del ginocchio Triathlon 19
Renovación parcial de rodilla Triathlon 25
Recobrimento de Joelho Parcial Triathlon 31
Triathlon delknäprotes 37
Triathlon- polven osittaispinnoite 43
Triathlon partiel knæ-overfladebehandling 49
Triathlon partiële knie-resurfacing 55
Triathlon delvis kne-overflatebehandling 61
Urządzenie Triathlon do częściowej alloplastyki stawu kolanowego 67
Μερική αποκατάσταση επιφάνειας γονάτου Triathlon 73
Triathlon 局部膝关节表面置换 80
Triathlon 부분 슬부 표면복구 85
Triathlon部分的膝関節面再建術 92

QIN 4388, Ver. AB ECN Release Date: Apr 27, 2
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English

TRIATHLON PARTIAL KNEE RESURFACING

Description

The TRIATHLON Partial Knee Resurfacing device is a modular unicondylar knee prostheses consisting of sterile, single-use components intended for replacement of the femoral condyle regions for either the right or left knee. The characteristics specific for each component are detailed on the product label.

Materials:

• Femoral Components	ASTM F-75, cobalt chromium alloy
• Modular Tibial Trays	ASTM F-75, cobalt chromium alloy
• Tibial Inserts	ASTM F-648, Ultra high molecular weight polyethylene

Indications for Use

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis;
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis;
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis; or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau. These components are intended for implantation with bone cement.

Contraindications

1. Patient has an active or suspected latent infection in or about the knee joint.
2. Patient has a known sensitivity to device materials.
3. Patient's bone stock is compromised by disease and/or infection, or prior implantation which cannot provide adequate support and/or fixation cannot be provided to the prosthesis.
4. Patients with inflammatory arthritis.
5. Patients with major deformity affecting the mechanical axis of the knee or neuromuscular disorders compromising motor control and/or stability.
6. Any mental or neuromuscular disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
7. Skeletal immaturity.
8. Ligamentous instability such that the postoperative stability afforded by the unicompartmental knee prosthesis would be compromised such as multidirectional/ACL instability.
9. Untreated damage to the contralateral compartment or the ipsilateral knee not being replaced by a prosthesis.
10. Untreated deterioration or destruction of the patello-femoral joint.
11. Severe deformity and/or recurrent subluxation of the knee joint.
12. Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of fixation of the device or failure of the device itself.
13. Severe tibial bone loss/deformity (over 15 degrees varus).

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Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. The surgeon should instruct the patient in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected in normal healthy bone, and the surgeon must instruct the patient not have unrealistic functional expectations.
- Appropriate selection, placement and fixation of the knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biological, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service. **The surgeon should warn the patient about these limitations.**
- Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.
- Surgeons should warn patients with metallic implants of the potential risks of undergoing a Magnetic Resonance Imaging (MRI) scan. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects. In addition, the presence of a metallic implant can produce an image artifact that may appear as a void region or geometric distortion of the true image. If the image artifact is near the area of interest, it may make the MRI scan uninformative or may lead to inaccurate clinical diagnosis or treatment.

MRI Safety Information

- The Triathlon Partial Knee Resurfacing system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Triathlon Partial Knee Resurfacing system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Utilization and Implantation

- See the appropriate surgical protocol which provides additional procedural information.
- The recommended trial components are used for size determination, trial reduction and range of motion evaluation. This preserves the integrity of the actual implants and their sterile packaging. Radiographic templates are also available to assist in the preoperative predication of component size.

Information for patients

- The surgeon must warn patients of surgical risks, and inform them of possible adverse effects. The surgeon must warn patients that the implant does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint, that the implant can break or become damaged for numerous reasons, including as a result of strenuous activity or trauma, and that the implant has a finite service life and may need to be replaced in the future.
- The surgeon must warn patients of the limitations of the reconstruction and the need to protect the implant from full weight bearing until adequate fixation and healing have occurred. The surgeon must advise the patient to limit activities and protect the implant from strenuous activity, trauma or impact loading, and to follow the surgeon's instructions regarding activity level, follow-up care, and treatment.
- The surgeon must advise patients that the implant cannot be expected to withstand the same activity levels and loads as a normal healthy joint, and that the implant will not restore function to the level expected with normal healthy bone. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the implant, or both. The surgeon must advise the patient against having unrealistic functional expectations.

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- The surgeon must warn patients that strenuous activity, trauma or impact loading affecting the implant have been implicated in failure of the implant by loosening, fracture and/or wear of the implants. Many factors, including loosening of the implant components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other surgical procedures have also been associated with transient bacteremia. To help minimize the risk of infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures. Surgeons should advise the patient to inform their doctors/dentists if they have an artificial joint replacement so that a decision can be made regarding antibiotic prophylaxis for such procedures.

Warnings

- Choose the correct size of implant. Position it and fix into place with bone cement with care.
- The femorotibial components of the Triathlon PKR System are not intended for repair of both condyles of the same knee simultaneously
- Discard all damaged or mishandled implants.
- Never reuse and implant, even though it may appear undamaged.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Except where noted, Howmedica Osteonics Corp. advises that a surgeon must not use another manufacturer's knee component with any HOWMEDICA OSTEONICS Knee Component. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Intentional removal of a knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.
- Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**
- Patient post-operative pain. Inherent to all joint replacement is the risk that a patient will develop post-operative pain; pain is a commonly reported symptom regardless of the device implanted. The clinical literature reveals numerous potential causes of pain not directly related to the implant performance including, but not limited to, prior history of trauma and natural disease progression.

  For patients who present with pain following implantation of any orthopedic implant system, the physician should consider all potential causes of the symptoms identified in the clinical literature, including infection, soft tissue impingement, and possible adverse local tissue reactions associated with wear debris, metal ions or corrosion. Accurate diagnosis of the source of pain and directed, timely intervention is essential to ensuring effective treatment of pain.
- Always use components from the appropriate system, as components from the different unicondylar prosthesis cannot be mixed and matched. The Triathlon Partial Knee replacement femoral component must be used with a Triathlon Partial Knee Replacement tibial component.

Adverse Effects

- While the expected life of knee replacement components is difficult to estimate, it is finite.
- These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated *in vivo*, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Dislocation of the prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations. Muscle and fibrous tissue laxity can also contribute to these conditions.

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- Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Although rare, sensitivity/allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.
- Polyethylene particles and metal particles from mechanisms other than wear. Very small particles from metal and polyethylene components can be shed from non-articulating surfaces during normal use and over time. Although most of these particles stay in the relevant joint (i.e. contained in the synovium) or are trapped by surrounding scar tissue, microscopic particles can migrate throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. The long-term effects, if any, from these particles, are unknown. The long-term effects have been theorized to include:
  - Cancer: There is presently no scientific evidence that links metallic or polyethylene particles with cancer. However, the possibility cannot be ruled out.
  - Lymphadenopathy and Accumulation in Other Tissues/Organs: There have been a few reports of the accumulation of particles in lymph nodes (proximal and distal). Although no medical complications or disease process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
  - Systemic Disease: It is possible that some long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of particles and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.
- Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components. (See IMPORTANT PHYSICIAN INFORMATION section for more information.)

Important Physician Information

Bone Resorption and Osteolysis. Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion,

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abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence. Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

Sterilization

- This knee component has been sterilized by gamma radiation or hydrogen peroxide gas plasma. Refer to the package label for the sterilization method.
- Do not resterilize.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.
- Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
- If the package is opened, but the product is not used, the component **must not** be resterilized and must be discarded or returned to the supplier.
- Single use devices cannot be explanted and subsequently reimplanted as the physical forces exerted by these actions may compromise the physical integrity, dimensions and/or surface finishes of the devices. Also, sterility cannot be assured for reused devices as cleaning and re-sterilization procedures have not been verified.
- Device should not be used after the expiry date displayed on the label as packaging had not been validated beyond this date.

CAUTION: **FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.**

WARNING: **THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.**

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks: Howmedica, Osteonics, Stryker, Triathlon. All other trademarks or service marks are trademarks and service marks of their respective owners or holders.

Refer to product label for CE Mark Status and Legal Manufacturer. The CE mark is only valid if also found on the product label.

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The following table contains a list of abbreviations that are used on Howmedica Osteonics Corp. product labeling:

Term	Abbreviation	Term	Abbreviation
Alpha Code	ALPH CDE	Neck	NK
Angle	ANG	Offset	OFFST
Degree	DEG or °	Outer Diameter	OD
Diameter	DIA	Right	RT ▶
Extra Deep	XDP	Screw Holes	SCR HLS
Extra Large	XLGE	Side	SDE
Extra Small	XSM	Size	SZE
Head	HD	Small	SM
Height	HT	Standard	STD
Inner Diameter	ID	Taper	TPR
Insert	INSR	Thickness	THKNS
Large	LGE	Type	TYP
Left	◀ LFT	With	W/
Length	LNTH	Without	W/O
Medium	MED		

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Appendix D

Model Informed Consent Form

CONFIDENTIAL
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MODEL INFORMED CONSENT FORM

I. Study Title: A retrospective enrolled, prospectively followed, multi-center evaluation of clinical outcomes of the Triathlon PKR Knee System

II. Description of the Study and Your Participation in the Study

You are being asked to take part in this research study because you have a Triathlon PKR Knee. The first phase of the study started in 2010 where patients were enrolled at the time of their surgery. There were not enough patients that enrolled in that phase of the study, so we are recruiting patients like you that had the Triathlon PKR knee implanted before the study started or after the surgeon met the number originally committed to. By adding your important information on your knee function to our current information we will have more data to complete the study protocol. Your surgeon is a study investigator on the study.

We (Stryker, implant manufacturer and Sponsor of this study, and your physician) are doing this study to find out if the Stryker Triathlon PKR Total Knee System functions similar to the Triathlon CR total knee system. We would like to obtain 10-year data to compare the function of these two knee devices.

Before any study-related procedures are completed, you will be asked to read and sign this consent document. Once signed, the doctor and the staff will review your medical records to make sure you are eligible to participate in the study. If you meet the study requirements, the doctor's staff will collect your clinical information related to having this knee surgery and your clinical information after your surgery. Your doctor can answer any questions you might have about the study before you decide to participate. Your participation in this study is voluntary. You can tell your doctor that you do not want to be a part of the study. If selected, your participation in the study will be until you reach your 10-year postoperative anniversary. Depending on the date of your original surgery, your first visit will be scheduled for either a five-year postoperative visit or a 10-year postoperative visit. At these two visits, the doctor will assess the function of your knee and ask you to complete four general health assessment questionnaires either in the office during your follow-up visit, or via mail before or after your visit. X-rays on your knee would be useful but are optional.

III. Possible Risks and Discomforts

There are no additional risks associated with participating in this study. Your privacy is very important, and your surgeon and Sponsor will take precautions to protect your privacy but cannot guarantee that your identity will never become known. It is possible that there could be security breaches of the computer systems used to store your medical information. There may also be other privacy risks that we have not foreseen.

Talk to your doctor if you have any questions about any risks associated with participating in this study.

There may be risks from participating in this study that are unknown.

Patient's Initials _____

Version: _____

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IV. Potential Benefits

You might not receive any benefits from being in the study, but the results might help others that have knee surgery in the future.

V. Other Types of Treatment

You may decline to participate in this study. This will not change any follow-up or care associated with your knee surgery.

VI. Make Financial Information Known

Your doctor and/or the research institution may receive compensation from the Sponsor, which is the company that made the implant device, to cover the time and/or expenses associated with this Study or for other services. This money will be used to pay for the cost of doing the study or for other reasons. If you require any further information, please consult your doctor or his staff about this issue.

VII. Confidentiality

Once you sign this consent form, you allow your doctor, his or her staff and the hospital to give information about your health to the Sponsor, and you allow the Sponsor to see and use your health information and other information collected during, or in connection with, the study, as described in this consent.

Other people or groups that may see information about your health and other information collected in this study include:

- Sponsor affiliates
- The investigator who conducts this study and his or her research staff.
- Government bodies, such as the FDA, that may inspect all records relating to the study.
- People who ensure that medical treatment and research studies are safe, such as the institutional review board that reviews the study.

Some of the persons and groups listed above may not be required by law to protect your health information to the same extent as your doctor and the hospital. Once your health information has been released, it may be redisclosed or used for other purposes.

You have the right to refuse to sign this consent form, but if you do not sign it, you will not be able to participate in this study. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.

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This permission to release and use your health information does not have an end date. You can take back this permission at any time by telling your doctor in writing. If you take back this permission, you cannot be in the study anymore. If you take back this permission, it will not change the work that has already been done in the study, and the Sponsor may keep and use information that has already been collected.

By signing this consent form, you give the Sponsor permission to store your data in one or more password-protected databases accessible only by Sponsor and use such data for the purposes described in this consent form. Such databases may be located at an international Stryker or a third-party location and may be accessible to Stryker personnel worldwide. As also described herein, in the course of administering this study, Sponsor personnel will see a copy of your signed consent with your personal information to verify you agreed to participate in this study, but such copies will not be generally accessible and will not be maintained in Sponsor's records.

VIII. Cost to Participate in Study

Your office clinical visit at 5-years, 7-years and 10-years after surgery, may be covered by your insurance carrier. If it is not, the sponsor of the study will reimburse costs due to lost insurance or lack of insurance coverage on a case by case review. Additionally, you will be offered a stipend for the 5-year, 7-year and 10-year follow-up visits. You will be paid in the form of a debit/cash card at the completion of these follow-up visits.

IX. Device Retrieval Analysis

I understand that the Stryker Triathlon PKR Outcomes Study has a protocol for the analysis of retrieved devices if any study component(s) that I have had implanted by Dr. <Investigator's Name> are removed during the investigation.

I understand that Stryker (implant manufacturer and Sponsor), requests my Physician to send my retrieved study component(s) to the Product Surveillance department at Stryker for evaluation as part of my participation in the study.

I hereby authorize my Physician and his staff to provide my retrieved study component(s), name, birth date, and any and all information about my knee surgery to Stryker for the purposes of evaluating my retrieved device(s) and reporting the results of the analysis to my Physician and Stryker Corporation.

My Physician will be provided with the results of this analysis. I understand that the device(s) will not be returned to me, nor will I receive the results of any tests, analysis, or evaluations on the returned device(s).

I understand that, except for sending my retrieved study component(s) to Stryker, my retrieved study component(s) will not be released to outside parties.

Patient's Initials _____

Version: _____

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I understand that, except for providing my individually identifiable information to the Physician who performed my surgery and Stryker, my individually identifiable data will not be released to outside parties. I also understand that I may inspect or copy the information by requesting said information from my Physician.

I understand that I may revoke this authorization for release of my retrieved study component(s) and individually identifiable information at any time by notifying my Physician in writing, but I understand that doing so will have no effect on actions taken before the receipt of my revocation.

I will have confidentiality in all records kept about me. My agreement to participate in this implant retrieval analysis study is completely voluntary. I understand that I have the right to not participate and the right to withdraw from the study at any time of my choosing and that this will in no way compromise my care, delay my treatment, or affect any future medical care.

I, the undersigned, have read and understood the above and agree to participate in the implant retrieval analysis study, and I hereby consent to the release of my retrieved study component(s) and my individually identifiable information under the conditions stated above. My signature indicates that I have had the opportunity to ask questions about the device retrieval study, have had my questions answered to my satisfaction and that I have received a copy of the consent form.

_____ _____

Signature of Subject/Legal Representative Date

X. Clinical Trial Website Posting

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

XI. Injury Related Compensation and Medical Treatment

Stryker will not provide compensation or free medical treatment if you suffer any medical complications related to the surgery. <Investigator's name> should be contacted immediately at <Investigator's phone number> if such a complication occurs. No monetary compensation or free medical treatment will be made available by <Name of Hospital>. <Investigator's name> should inform you of the hospital's policy in such matters. Signing this consent in no way waives your legal rights or releases the investigator, the sponsor, the institution or its agents from liability or negligence.

Patient's Initials _____

Version: _____

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XII. Use of Data Collected as Part of the Study

The Sponsor will use the information collected during the study for the purposes described in this consent, and for any future anticipated or unanticipated scientific uses as the Sponsor or other third parties may deem appropriate. The information collected is necessary to support the objectives of the research.

The sponsor will use your health information to conduct the study, as well as for additional purposes, such as overseeing and improving the performance of its devices, proposals for developing new medical products or procedures and other business purposes.

XIII. Contact Information

During the study, if you experience any medical problems, suffer an injury, or have questions, concerns or complaints about the study, please contact the study doctor at <names and phone numbers>. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in a research study being conducted by the <name>. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should contact <IRB Information>.

XIV. New Findings

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

XV. Voluntary Participation/Withdrawal

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, your images and data may remain in storage and use, as described in this consent for an indefinite period.
You may withdraw consent up until your images and data are de-identified. If you withdraw your consent before de-identification, Sponsor will no longer disseminate your data and images, but your data and images already collected and used may remain part of the Sponsor's database and may not be removed in order to ensure the scientific validity of the Study. After your images and data are de-identified you will not be able to withdraw consent for your images and data to be retrieved or not further disseminated, stored, or used.

The study doctor or sponsor can stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, if the study is canceled, or for administrative reasons including competitive enrollment - the target number of subjects has entered the study.

Patient's Initials _____

Version: _____

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Being part of this study is your choice. If you decline to participate in the study, it will not prejudice your care. By signing and dating this form below, you are saying you have carefully read all the sections of this Informed Consent Form. You are also saying someone has answered all your questions and that you voluntarily consent to be in this research study. If you do not sign this form, you will not be able to take part in the research study.

_____
Printed name of Subject/Legal Representative

_____ _____
Signature of Subject/Legal Representative Date Signed

(additional signatures that may be required):

_____ _____
Signature of Person conducting the consent process Date Signed

_____ _____
Signature of Investigator Date Signed

A signed and dated copy of this consent form must be given to the patient.

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Appendix E

Sample Case Report Forms

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325 Corporate Drive, Mahwah, NJ 07430

Triathlon PKR Outcomes Study
INCLUSION / EXCLUSION

PATIENT ID: 6 6 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

I. INCLUSION CRITERIA

DATE INFORMED CONSENT SIGNED: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

	Yes	No	
1.	○	○	The subject is a male or non-pregnant female 21-75 years of age at the time of enrollment.
2.	○	○	The subject requires a primary cemented unicompartmental knee replacement.
3.	○	○	The subject has a diagnosis of osteoarthritis (OA), or post-traumatic arthritis (TA).
4.	○	○	The subject has clinically intact cruciate and collateral ligaments and no ligamentous instability is present.
5.	○	○	The subject has less than 10 degrees of flexion contracture and greater than 90 degrees of flexion.
6.	○	○	The subject's preoperative mechanical alignment is less than 10 degrees of varus and 10 degrees of valgus.
7.	○	○	The subject has signed the IRB approved study specific Informed Patient Consent Form.
8.	○	○	The subject is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

**** All of the above must be answered "Yes" for the patient to be enrolled in the study.**

II. EXCLUSION CRITERIA

	Yes	No	
1.	○	○	The subject has inflammatory arthritis or avascular necrosis (AVN).
2.	○	○	The subject is obese, BMI > 35.
3.	○	○	The subject has a history of total or unicompartmental (contralateral compartment and/or patellofemoral joint) reconstruction of the affected joint.
4.	○	○	The subject has a history of ACL reconstruction.
5.	○	○	The subject has had a high distal femoral, or proximal tibial osteotomy.
6.	○	○	The subject has a mental, neuromuscular or neurosensory disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care and/or limit the ability to assess the performance of the device.
7.	○	○	The subject has a systemic or metabolic disorder leading to progressive bone deterioration that the surgeon feels would affect the overall outcome of the study.
8.	○	○	The subject is immunologically suppressed, or is receiving chronic steroids (>30 days duration).
9.	○	○	The subject has a known sensitivity to device materials.
10.	○	○	The subject's bone stock is compromised by disease and/or infection which cannot provide adequate support and/or fixation to the prosthesis.
11.	○	○	The subject's bone stock is compromised by a prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
12.	○	○	The subject has an active or suspected latent infection in or about the knee joint.
13.	○	○	The subject is a prisoner.

**** All of the above must be answered "No" for the patient to be enrolled in the study.**

Please fax to Stryker at (201) 831-6454 attn: Study Manager for a patient ID to be assigned.

III. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

For Stryker Use Only

Stamp Date Received:

INITIAL/DATE:
Receipt ____
Entry ____
Verification ____
Monitored ____

Stryker®

325 Corporate Drive, Mahwah, NJ 07430

Triathlon PKR Outcomes Study
DEMOGRAPHICS

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

VISIT DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

I. DEMOGRAPHICS

A. DATE OF BIRTH: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

B. HEIGHT: ☐☐☐ inches

C. WEIGHT: ☐☐☐ lbs.

D. EDUCATION LEVEL: (Check One)

○ < High School ○ High School Diploma ○ > High School

E. EMPLOYMENT STATUS: (Check One)

○ Working ○ Not working

F. GENDER: (Check one)

○ Male ○ Female

G. ETHNICITY: (Check one)

○ Hispanic or Latino origin

○ Not Hispanic or Latino origin

H. RACE: (Check all that apply)

☐ American Indian or Alaskan native

☐ Asian

☐ Black or African heritage

☐ Native Hawaiian or other Pacific Islander

☐ White

II. CIGARETTE SMOKING AND ALCOHOL HISTORY

I. CIGARETTE USE: (Check One)

○ Non-smoker

○ Current cigarette smoker

PACKS/DAY: ☐.☐ # YEARS: ☐☐.☐

○ Ex-cigarette smoker

PACKS/DAY: ☐.☐ # YEARS: ☐☐.☐

Date Stopped ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

J. ALCOHOL USE: (Check One)

○ Have never had alcohol

○ Have not had alcohol in the last year

○ < 3 drinks a week

○ 3 - 7 drinks a week

○ 8 - 14 drinks a week

○ 15+ drinks a week

III. DIAGNOSIS

K. INITIAL DIAGNOSIS: (Check One)

○ Osteoarthritis ○ Traumatic Arthritis

○ Other (Specify) _____

(If Other, complete Study Termination form)

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Triathlon PKR Outcomes Study

DEMOGRAPHICS

PATIENT ID: 6 6 | Site # | Subject #

GENERAL INFORMATION

PATIENT INITIALS:
(If there is no middle initial please use "-")

IV. PRESENT MEDICAL STATUS

L. CONCURRENT MEDICAL CONDITION: (Specify)

- ☐ None
- ☐ Cancer _____
- ☐ Cardiovascular _____
- ☐ Dermatologic _____
- ☐ Digestive _____
- ☐ Endocrine / Metabolic _____
- ☐ Immunologic / Lymphatic _____
- ☐ Musculoskeletal _____
- ☐ Neurologic _____
- ☐ Psychologic _____
- ☐ Respiratory _____
- ☐ Substance Dependence _____
- ☐ Urogenital _____
- ☐ Other (Specify) _____

V. COMMENTS

_____

_____

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: D D / M M M / Y Y Y Y

For Stryker Use Only

Stamp Date Received:

INITIAL/DATE:
Receipt _____
Entry _____
Verification _____
Monitored _____

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Triathlon PKR Outcomes Study
PRE-OP FUNCTIONAL EVALUATION - KSS

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

VISIT DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check one)

I. KSS

A. PATIENT CATEGORY: (Check one)

- ○ Unilateral or Bilateral (opposite knee successfully replaced)
- ○ Unilateral, Other Knee Symptomatic
- ○ Multiple Arthritis or Medical Infirmity (specify) _____

II. KSS - PAIN/MOTION SCORE

B. PAIN: (Check one)

- ○ None
- ○ Mild or Occasional
- ○ Mild or Occasional, Stairs Only
- ○ Mild or Occasional, Walking & Stairs
- ○ Moderate Occasional
- ○ Moderate Continual
- ○ Severe

D. RANGE OF MOTION:

	Extension	Flexion
Active:	☐☐	☐☐☐
Passive:	☐☐	☐☐☐

C. STABILITY: (Amount of Motion)

Anteroposterior (Check one)
- ○ < 5 mm
- ○ 5 - 10 mm
- ○ > 10 mm

Mediolateral (Check one)
- ○ < 5°
- ○ 5° - 9°
- ○ 10° - 14°
- ○ > 14°

E. ALIGNMENT - TIBIO-FEMORAL ANGLE: (Check one)

- ○ Valgus ☐☐ °
- ○ Varus ☐☐ °

III. KSS - FUNCTION SCORE

F. WALKING: (Check one)
- ○ Unlimited
- ○ > 10 Blocks
- ○ 5 - 10 Blocks
- ○ < 5 Blocks
- ○ Housebound
- ○ Unable

G. STAIRS: (Check one)
- ○ Normal Up & Down
- ○ Normal Up; Down with Rail
- ○ Up & Down with Rail
- ○ Up with Rail; Unable Down
- ○ Unable

H. WALKING AIDS: (Check one)
- ○ None
- ○ Cane
- ○ Two Canes / One Crutch
- ○ Crutches or Walker; Cannot Walk / Wheelchair

IV. COMMENTS

_____

_____

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

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Triathlon PKR Outcomes Study
Pre-op Activity Questionnaire

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS:
(If there is no middle initial please use "-")

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

I. ACTIVITY QUESTIONNAIRE

The device is not intended to restore function to the same levels expected in normal healthy individuals. Activities post surgery will be limited. You should consult your physician regarding appropriate post-surgery activities and any other related questions or concerns.

Circle a Number to answer each of the following:

1) How would you describe your overall activity/energy level?

Very Sedentary 0 1 2 3 4 5 6 7 8 9 10 Extremely Active

2) Please rate your competitiveness prior to surgery.

Noncompetitive 0 1 2 3 4 5 6 7 8 9 10 Very Competitive

3) Please check one regarding recreational or sport activities.

- ○ **I do not currently participate because my knee keeps me from participating.**
- ○ **I do not currently participate because my general physical condition (other than my knee) keeps me from participating.**
- ○ **I do not currently participate because I do not like to do recreational or sport activities.**
- ○ **I currently participate and the activities are listed below.**

If you <u>do not</u> participate in any activities, do not complete the rest of the form. Please initial and date the bottom of the form.

Activity	How many times a WEEK do you do this?	How long do you do this activity on average per session?	Activity	How many times a WEEK do you do this?	How long do you do this activity on average per session?
Example:					
Walk	*3*	*30 mins*			mins
		mins			mins
		mins			mins
		mins			mins
		mins			mins

4) How much did knee pain or stiffness limit your activity participation?

No limitation 0 1 2 3 4 5 6 7 8 9 10 Severe Limitation

5) How severe was your knee pain during the performed activities?

No pain 0 1 2 3 4 5 6 7 8 9 10 Severe Pain

Patient, please initial and date here:

DATE: D D / M M M / Y Y Y Y

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Triathlon PKR Outcomes Study

SF-12v2™

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-")

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

VISIT : ○ Pre-Op ○ 2 Wks ○ 6 Wks ○ 3 Months ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. SF-12

A. In general, would you say your health is: (check one)

Excellent	Very Good	Good	Fair	Poor
○	○	○	○	○

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (check one)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
B. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf (check one)	○	○	○
C. Climbing several flights of stairs (check one)	○	○	○

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (check one)

D. Accomplished less than you would like (check one)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

E. Were limited in the kind of work or other activities (check one)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (check one)

F. Accomplished less than you would like (check one)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

G. Did work or other activities less carefully than usual (check one)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

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Triathlon PKR Outcomes Study

SF-12v2™

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-")

VISIT: ○ Pre-Op ○ 2 Wks ○ 6 Wks ○ 3 Months ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. SF-12 (continued)

H. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (check one)

Not at all ○ | A little bit ○ | Moderately ○ | Quite a bit ○ | Extremely ○

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

I. Have you felt calm and peaceful? (check one)

All of the time ○ | Most of the time ○ | Some of the time ○ | A little of the time ○ | None of the time ○

J. Did you have a lot of energy? (check one)

All of the time ○ | Most of the time ○ | Some of the time ○ | A little of the time ○ | None of the time ○

K. Have you felt downhearted and depressed? (check one)

All of the time ○ | Most of the time ○ | Some of the time ○ | A little of the time ○ | None of the time ○

L. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? (check one)

All of the time ○ | Most of the time ○ | Some of the time ○ | A little of the time ○ | None of the time ○

Patient, please initial and date here:

DATE: D D / M M M / Y Y Y Y

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Triathlon PKR Outcomes Study

LOWER EXTREMITY ACTIVITY SCALE

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-")

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

VISIT : ○ Pre-Op ○ 2 Wks ○ 6 Wks ○ 3 Months ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. LOWER EXTREMITY ACTIVITY SCALE

Please read through each description given below, pick ONE description that best describes your regular daily activity, and mark that circle.

CHECK ONE ONLY

A. ○ I am confined to bed all day.

B. ○ I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc).

C. ○ I am either in bed or sitting most of the day.

D. ○ I sit most of the day, except for minimal transfer activities, no walking or standing.

E. ○ I sit most of the day, but I stand occasionally and walk a minimal amount in my house (I may rarely leave the house for an appointment and may require the use of a wheelchair or scooter for transportation).

F. ○ I walk around my house to a moderate degree but I don't leave the house on a regular basis (I may leave the house occasionally for an appointment).

G. ○ I walk around my house and go outside at will, walking one or two blocks at a time.

H. ○ I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting).

I. ○ I am up and about at will in my house and can go out and walk as much as I would like with no restrictions (weather permitting).

J. ○ I am up and about at will inside my house and outside. I also work outside the house in a: **(check one)**

○ **minimally** active job ○ **moderately** active job ○ **extremely** active job

K. ○ I am up and about at will inside my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming: **(check one)**

○ **occasionally (2-3 times per month)** ○ **2-3 times per week** ○ **daily**

L. ○ I am up and about at will inside my house and outside. I also participate in vigorous physical activity such as competitive level sports: **(check one)**

○ **occasionally (2-3 times per month)** ○ **2-3 times per week** ○ **daily**

Patient, please initial and date here:

DATE: D D / M M M / Y Y Y Y

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INITIAL/DATE:

Receipt _____

Entry _____

Verification _____

Monitored _____

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Triathlon PKR Outcomes Study
KOOS KNEE SURVEY

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use " - ")

OPERATIVE SIDE: (Use one form per side) ○ Right ○ Left

VISIT: ○ Pre-op ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities.

Answer every question by checking the appropriate circle, only one circle for each question. If you are unsure about how to answer a question, please give the best answer you can.
Thank you for completing this survey!

I. SYMPTOMS

*These questions should be answered thinking of your knee symptoms during the **last week**.*

	Never	Rarely	Sometimes	Often	Always
A. Do you have swelling in your knee?	○	○	○	○	○
B. Do you feel grinding, hear clicking or any other type of noise when your knee moves?	○	○	○	○	○
C. Does your knee catch or hang up when moving?	○	○	○	○	○
D. Can you straighten your knee fully?	○	○	○	○	○
E. Can you bend your knee fully?	○	○	○	○	○

II. STIFFNESS

*The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.*

	None	Mild	Moderate	Severe	Extreme
A. How severe is your knee joint stiffness after first waking in the morning?	○	○	○	○	○
B. How severe is your knee stiffness after sitting, lying or resting **later in the day**?	○	○	○	○	○

III. PAIN

A. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
○	○	○	○	○

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Triathlon PKR Outcomes Study

KOOS KNEE SURVEY

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use " - ")

OPERATIVE SIDE: (Use one form per side) ○ Right ○ Left

VISIT : ○ Pre-op ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

III. PAIN

*What amount of knee pain have you experienced in the **last week** during the following activities?*

	None	Mild	Moderate	Severe	Extreme
B. Twisting/pivoting on your knee?	○	○	○	○	○
C. Straightening knee fully?	○	○	○	○	○
D. Bending knee fully?	○	○	○	○	○
E. Walking on flat surface?	○	○	○	○	○
F. Going up or down stairs?	○	○	○	○	○
G. At night while in bed?	○	○	○	○	○
H. Sitting or lying?	○	○	○	○	○
I. Standing upright?	○	○	○	○	○

IV. FUNCTION - DAILY LIVING

*The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced during the **last week** due to your knee.*

	None	Mild	Moderate	Severe	Extreme
A. Descending stairs?	○	○	○	○	○
B. Ascending stairs?	○	○	○	○	○
C. Rising from sitting?	○	○	○	○	○
D. Standing?	○	○	○	○	○
E. Bending to floor/pick up an object?	○	○	○	○	○
F. Walking on flat surface?	○	○	○	○	○
G. Getting in/out of car?	○	○	○	○	○
H. Going shopping?	○	○	○	○	○
I. Putting on socks/stockings?	○	○	○	○	○
J. Rising from bed?	○	○	○	○	○
K. Taking off socks/stockings?	○	○	○	○	○
L. Lying in bed (turning over, maintaining knee position)?	○	○	○	○	○
M. Getting in/out of bath?	○	○	○	○	○
N. Sitting?	○	○	○	○	○

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Triathlon PKR Outcomes Study

KOOS KNEE SURVEY

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

OPERATIVE SIDE: (Use one form per side) ○ Right ○ Left

VISIT : ○ Pre-op ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

IV. FUNCTION - DAILY LIVING

*For each of the following activities please indicate the degree of difficulty you have experienced during the **last week** due to your knee.*

	None	Mild	Moderate	Severe	Extreme
O. Getting on/off toilet?	○	○	○	○	○
P. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)?	○	○	○	○	○
Q. Light domestic duties (cooking, dusting, etc)?	○	○	○	○	○

V. FUNCTION - SPORTS AND RECREATIONAL ACTIVITIES

*The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.*

	None	Mild	Moderate	Severe	Extreme
A. Squatting?	○	○	○	○	○
B. Running?	○	○	○	○	○
C. Jumping?	○	○	○	○	○
D. Twisting/pivoting on your injured knee?	○	○	○	○	○
E. Kneeling?	○	○	○	○	○

VI. QUALITY OF LIFE

A. How often are you aware of your knee problem?

Never ○ | Monthly ○ | Weekly ○ | Daily ○ | Constantly ○

B. Have you modified your lifestyle to avoid potentially damaging activities to your knee?

Not at all ○ | Mildly ○ | Moderately ○ | Severely ○ | Totally ○

C. How much are you troubled with lack of confidence in your knee?

Not at all ○ | Mildly ○ | Moderately ○ | Severely ○ | Totally ○

D. In general, how much difficulty do you have with your knee?

None ○ | Mild ○ | Moderate ○ | Severe ○ | Extreme ○

Patient, please initial and date here:

DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

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Triathlon PKR Outcomes Study
SURGICAL DETAILS

PATIENT ID: 6 6 (Study #) ☐☐ (Site #) ☐☐☐☐ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

II. FIT

J. PROSTHESIS: (Complete for each)

	Reference #	Lot Code #
Femoral Component:		
Tibial Component / Metal Tray:		
Tibial Insert:		

K. SOFT TISSUE RELEASED: (Check All That Apply)

- ☐ None
- ☐ Biceps Femoris Tendon
- ☐ Iliotibial Tract
- ☐ Lateral Collateral Ligament
- ☐ Lateral Head of Gastrocnemius
- ☐ Lateral Retinacular
- ☐ Medial Collateral Ligament ◯ Deep ◯ Superficial
- ☐ Popliteus Tendon
- ☐ Postero-Medial Capsule
- ☐ Postero-Lateral Capsule
- ☐ Other: (specify) _____

L. ESTIMATED BLOOD LOSS: ☐☐☐☐ cc

M. DURATION OF SURGERY:

- Skin to Skin: ☐☐☐ minutes
- Tourniquet: ☐☐☐ minutes
- First Jig to Final Component Placement: ☐☐☐ minutes

N. COMPARTMENT REPLACED: (Check One)
◯ Medial ◯ Lateral

O. ACL INTACT? (Check one)
◯ Yes ◯ No*
**If No, complete Protocol Deviation and Study Termination forms.*

P. INTRAOPERATIVE COMPLICATION?: (Check one)
◯ Yes* ◯ No
**If Yes, Complete an Adverse Event Form for Each Complication*

Q. AMBULATORY STATUS AT DISCHARGE: (Check One)
◯ Crutches ◯ Wheelchair
◯ Walker ◯ Other: (specify) _____

R. DISCHARGED TO: (Check One)
◯ Skilled Nursing Facility
◯ Chronic Care Center
◯ Rehabilitation Unit
◯ Home
◯ Other: (specify) _____

Discharge Date: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

III. COMMENTS

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

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Triathlon PKR Outcomes Study
SURGICAL DETAILS

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use " - ") ☐☐☐

SURGERY DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

OPERATIVE SIDE: (use one form per side) ◯ Right ◯ Left (Check One)

I. SURGICAL DETAILS

A. TYPE OF ANESTHESIA: (Check all that apply)

- ☐ General
- ☐ Spinal
- ☐ Epidural
- ☐ Femoral Block
- ☐ Sciatic Nerve Block

B. LENGTH OF SKIN INCISION: ☐☐☐ mm

C. INCISION (Check one) ◯ MIS ◯ Standard

D. SURGICAL APPROACH: (Check one)

◯ Medial Parapatellar ◯ Lateral Parapatellar

How far did the quadricep incision go past the superior pole of the patella? (Check one)

- ◯ at level of superior pole
- ◯ above the superior pole up to 1 cm
- ◯ above the superior pole up to 2 cm
- ◯ above the superior pole up to 3 cm
- ◯ > 3 cm above the superior pole

◯ Mid Vastus

Length of VMO Snip: (Check one)

- ◯ 0
- ◯ >0 - < 1.5 cm
- ◯ 1.5 - 3 cm
- ◯ > 3 cm

◯ Sub Vastus

E. NAVIGATION USED? ◯ Yes* ◯ No

***If Yes, complete the following:**

System Used/Manufacturer _____

Software Version _____

Intra-op PRE-Implant Long Limb (Mechanical) Alignment: ☐☐ °

◯ Valgus ◯ Varus

Tibial Cut Depth: ☐☐☐ mm

Distal Femur Cut Depth: ☐☐☐ mm

Tibial Varus/Valgus Angle: ☐☐ °

Tibial Slope: ☐☐ °

Intra-op POST-Implant Long Limb (Mechanical) Alignment: ☐☐ °

◯ Valgus ◯ Varus

F. SURGICAL RANGE OF MOTION:

Pre-op Extension: ☐☐° Pre-op Flexion: ☐☐☐ °

Post-op Extension: ☐☐° Post-op Flexion: ☐☐☐ °

G. BRAND OF CEMENT USED : (Check one)

◯ Simplex P ◯ Palacos ◯ Cobalt

◯ Other: (Specify) _____

H. BONE REMOVED: (Complete for each)

Distal Femur: ☐☐ mm Proximal Tibia: ☐☐ mm

Patella Facectomy Done? ◯ Yes ◯ No

I. OUTERBRIDGE CLASSIFICATION:

CONTRALATERAL COMPARTMENT: (Check one)	**PATELLO FEMORAL JOINT:** (Check one)
◯ Grade 0	◯ Grade 0
◯ Grade I	◯ Grade I
◯ Grade II	◯ Grade II
◯ Grade III	◯ Grade III
◯ Grade IV	◯ Grade IV

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Triathlon PKR Outcomes Study

POST-OP FUNCTIONAL EVALUATION - KSS

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ☐☐☐

VISIT DATE: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check one)

VISIT : ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year ○ Unscheduled (Specify reason in Comments)

I. WEIGHT

A. WEIGHT: ☐☐☐ lbs.

II. KSS

B. PATIENT CATEGORY: (Check one)

- ○ Unilateral or Bilateral (opposite knee successfully replaced)
- ○ Unilateral, Other Knee Symptomatic
- ○ Multiple Arthritis or Medical Infirmity (specify) _____

III. KSS - PAIN/MOTION SCORE

C. PAIN: (Check one)

- ○ None
- ○ Mild or Occasional
- ○ Mild or Occasional, Stairs Only
- ○ Mild or Occasional, Walking & Stairs
- ○ Moderate Occasional
- ○ Moderate Continual
- ○ Severe

D. RANGE OF MOTION:

	Extension	Flexion
Active:	☐☐	☐☐☐
Passive:	☐☐	☐☐☐

E. STABILITY: (Amount of Motion)

Anteroposterior (Check one)

- ○ < 5 mm
- ○ 5 - 10 mm
- ○ > 10 mm

Mediolateral (Check one)

- ○ < 5°
- ○ 5° - 9°
- ○ 10° - 14°
- ○ > 14°

F. ALIGNMENT - TIBIO-FEMORAL ANGLE: (Check one)

- ○ Valgus ☐☐ °
- ○ Varus ☐☐ °

IV. KSS - FUNCTION SCORE

G. WALKING: (Check one)

- ○ Unlimited
- ○ > 10 Blocks
- ○ 5 - 10 Blocks
- ○ < 5 Blocks
- ○ Housebound
- ○ Unable

H. STAIRS: (Check one)

- ○ Normal Up & Down
- ○ Normal Up; Down with Rail
- ○ Up & Down with Rail
- ○ Up with Rail; Unable Down
- ○ Unable

I. WALKING AIDS: (Check one)

- ○ None
- ○ Cane
- ○ Two Canes / One Crutch
- ○ Crutches or Walker; Cannot Walk / Wheelchair

V. OTHER

J. TRANSFER ACTIVITY - CHAIR TO STANDING: (Check one)

- ○ Without Upper Extremity Support
- ○ With Upper Extremity Support
- ○ Cannot Transfer

K. CREPITUS: (Check one)

- ○ Absent ○ Present

L. ANTERIOR KNEE PAIN: (Check one)

- ○ Absent
- ○ Present

If present at 1 yr or later, please explain _____

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Triathlon PKR Outcomes Study

POST-OP FUNCTIONAL EVALUATION - KSS

PATIENT ID: 6 6 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-")

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check one)

VISIT: ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year ○ Unscheduled (Specify reason in Comments)

VI. EVENTS

M. Have there been any protocol defined Adverse Events since the last visit? ○ Yes* ○ No

*If Yes, complete an AE form for each.

USE THIS SECTION TO REPORT MEDICAL EVENTS OTHER THAN PROTOCOL DEFINED ADVERSE EVENTS.

N. Has the patient seen a doctor for any medical event since the last visit? ○ Yes* ○ No

*If Yes, specify _____

O. Has the patient been hospitalized for any elective surgery since the last visit? ○ Yes* ○ No

*If Yes, specify (check all that apply)

☐ Contralateral Knee ☐ Contralateral Hip ☐ Ipsilateral Hip ☐ Contralateral Shoulder ☐ Ipsilateral Shoulder

☐ Cataract ☐ Other (specify) _____

*Provide Details _____

P. Is anything currently affecting the patient's function? ○ Yes* ○ No

*If Yes, specify _____

VII. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: D D / M M M / Y Y Y Y

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Entry _____

Verification _____

Monitored _____

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Triathlon PKR Outcomes Study
Post-op Activity Questionnaire

PATIENT ID: 6 6 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ____

OPERATIVE SIDE: ○ Right ○ Left (Check One)
(use one form per side)

VISIT: ○ 2 Week ○ 6 Week ○ 3 Month ○ 1 Year ○ 2 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. ACTIVITY QUESTIONNAIRE

The device is not intended to restore function to the same levels expected in normal healthy individuals. Activities post surgery will be limited. You should consult your physician regarding appropriate post-surgery activities and any other related questions or concerns.

Circle a Number to answer each of the following:

1) How would you describe your overall activity/energy level?

Very Sedentary 0 1 2 3 4 5 6 7 8 9 10 Extremely Active

2) Please rate your competitiveness.

Noncompetitive 0 1 2 3 4 5 6 7 8 9 10 Very Competitive

3) Please rate your current satisfaction with your surgery.

Unsatisfied 0 1 2 3 4 5 6 7 8 9 10 Extremely Satisfied

4) Have you completed your rehabilitation program? ○ Yes ○ No* * If No, please complete question **4a.**

4a) Please rate your commitment to your current rehabilitation program.

Low Priority 0 1 2 3 4 5 6 7 8 9 10 Extremely Committed

5) Please check one regarding recreational or sport activities.

- ○ **I do not currently participate because my knee keeps me from participating.**
- ○ **I do not currently participate because my general physical condition (other than my knee) keeps me from participating.**
- ○ **I do not currently participate because I do not like to do recreational or sport activities.**
- ○ **I currently participate and the activities are listed below.**

If you <u>do not</u> participate in any activities, do not complete the rest of the form. Please initial and date the bottom of the form.

Activity	How many times a WEEK do you do this?	How long do you do this activity on average per session?	Activity	How many times a WEEK do you do this?	How long do you do this activity on average per session?
Example:					
Walk	*3*	*30 mins*			mins
		mins			mins
		mins			mins
		mins			mins

6) How much did knee pain or stiffness limit your activity participation?

No limitation 0 1 2 3 4 5 6 7 8 9 10 Severe Limitation

7) How severe was your knee pain during the performed activities?

No pain 0 1 2 3 4 5 6 7 8 9 10 Severe Pain

Patient, please initial and date here:

DATE: ____/____/____ (D D / M M M / Y Y Y Y)

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INITIAL/DATE:
Receipt ____
Entry ____
Verification ____
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Triathlon PKR Outcomes Study
ADVERSE EVENT

PATIENT ID: 6 6 (Study #) ___ (Site #) ____ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use " - ") ___

DATE OF EVENT: D D / M M M / Y Y Y Y

OPERATIVE SIDE: (use one form per side) ◯ Right ◯ Left (Check One)

I. DESCRIPTION

(Check one event in Section A or Section B)

A. OPERATIVE SITE EVENTS

- ◯ Arthrofibrosis
- ◯ Deep Joint Infection
- ◯ Excessive Knee Pain
- ◯ Femoral Fracture
- ◯ Loosening Femoral Component
- ◯ Loosening Patellar Component
- ◯ Loosening Tibial Component
- ◯ Myositis Ossificans
- ◯ Patellar Component Dislocation
- ◯ Patellar Fracture
- ◯ Patellar Subluxation
- ◯ Patellar Tendon Rupture
- ◯ Peroneal Nerve Palsy
- ◯ Prosthesis Fracture / Femoral Component
- ◯ Prosthesis Fracture / Patellar Component
- ◯ Prosthesis Fracture / Tibial Component
- ◯ Prosthesis Fracture / Tibial Insert
- ◯ Reflex Sympathetic Dystrophy (RSD)
- ◯ Soft Tissue Trauma
- ◯ Superficial Wound Infection
- ◯ Supracondylar Fracture
- ◯ Tibial Component Subsidence
- ◯ Tibial Fracture
- ◯ Wound Hematoma
- ◯ Wound Related (Specify) ___
- ◯ Other (Specify) ___

B. SYSTEMIC EVENTS

- ◯ Bronchopulmonary (Specify) ___
- ◯ Carcinoma (Specify) ___
- ◯ Cardiovascular (Specify) ___
- ◯ DVT
- ◯ Dermatological (Specify) ___
- ◯ Gastrointestinal (Specify) ___
- ◯ Genitourinary (Specify) ___
- ◯ Neurosensory (Specify) ___
- ◯ Pulmonary Embolism
- ◯ Thrombophlebitis
- ◯ Trauma (Specify) ___
- ◯ Other (Specify) ___

C. WHEN DID THE EVENT OCCUR? (Check one)

◯ Pre-Op ◯ Intra-Op ◯ Post-Op

II. COMPLICATION / CONCURRENT MEDICAL EVENT

D. HISTORY OR CAUSATIVE EVENT?

◯ Yes ◯ No

(If Yes, specify signs, symptoms and diseases.) ___

E. DEVICE RELATED? (Check one)

◯ Yes ◯ No ◯ Uncertain

(If Yes or Uncertain, explain, complete PER form and fax all pages to Stryker within 24 hours.) ___

F. SERIOUSNESS Does this event meet the definition of serious? (Check all that apply)

- ☐ Resulted in inpatient hospitalization
- ☐ Resulted in prolonged existing hospitalization
- ☐ Resulted in persistent or significant disability/incapacity
- ☐ Resulted in permanent impairment of a body function or permanent damage to a body structure
- ☐ Necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure
- ☐ Was a life threatening situation
- ☐ Resulted in patient death
- ☐ None of the above

If any items other than "None of the above" are checked -- FAX all pages to Stryker within 24 hours.
Fax number: (201) 831-6454. Please include copies of applicable source documentation.

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Triathlon PKR Outcomes Study
ADVERSE EVENT

PATIENT ID: 6 6 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ____

DATE OF EVENT: D D / M M M / Y Y Y Y

III. TREATMENT

☐ None

For Stryker implants revised or removed, submit PER form and implant(s) to Stryker

REVISIONS / REMOVAL: (Check all that apply)

Date of Treatment

☐ Femoral Component — D D / M M M / Y Y Y Y

☐ Tibial Component — D D / M M M / Y Y Y Y

☐ Tibial Insert — D D / M M M / Y Y Y Y

RE-OPERATIONS: (Specify)

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

OTHER TREATMENT: (Specify)

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

☐ _____ — D D / M M M / Y Y Y Y

RESOLUTION OF EVENT:

○ Unresolved as of — D D / M M M / Y Y Y Y

○ Resolved as of — D D / M M M / Y Y Y Y *

* Submit copy of this form when event resolved.

For Stryker Use Only PER# _____ ***Updated*** _____

IV. COMMENTS

_____

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: D D / M M M / Y Y Y Y

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Triathlon PKR Outcomes Study
STUDY TERMINATION

PATIENT ID: 6 6 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

PATIENT INITIALS: (If there is no middle initial please use "-") ____

OPERATIVE SIDE: (use one form per side) ○ Right ○ Left (Check One)

I. STUDY TERMINATION

A. DID PATIENT COMPLETE STUDY ACCORDING TO PROTOCOL? ○ Yes ○ No * If No, answer questions B and C

TERMINATION DATE: ____/____/____ (D D / M M M / Y Y Y Y)

B. CHECK ONE PRIMARY REASON BELOW:

○ Death (Complete AE form)

○ Investigative Site Terminated

○ Lost To Follow-Up

List efforts to contact patient:

1st phone call: ____/____/____

2nd phone call: ____/____/____

3rd phone call: ____/____/____

Certified letter sent: ____/____/____ (D D / M M M / Y Y Y Y)

Additional efforts: _____

○ Patient Withdrawal

○ Revision/Removal of Study Device (Complete AE form)

○ Study Device Not Implanted (Complete Surgical Details form and Protocol Deviation form) (Specify)

_____

○ Surgery Not Performed (Specify) _____

○ Other (Specify) _____

C. WAS STUDY DEVICE IN PLACE AT DATE OF LAST CONTACT? ○ Yes ○ No

II. COMMENTS

_____

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

DATE: ____/____/____ (D D / M M M / Y Y Y Y)

For Stryker Use Only

Stamp Date Received:

INITIAL/DATE:
Receipt _____
Entry _____
Verification _____
Monitored _____

Appendix F

Patient Retention Program

- Retention Program Details
- Comprehensive Booklet of all levels
- A sample patient booklet cover page for an individual level

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Triathlon® PKR Outcomes Study
Patient Retention Program
DETAILS

The intent of the program is to provide a subject with a gift equivalent to the level in which they have completed if they decide to withdraw from the study – all points collected at that time point will be redeemed for one gift. A patient can collect up to the maximum of 200 points at the 10-year visit if all visits previously were completed.
The following grid is to assist the sites in understanding the breakdown of the patient retention program:

LEVEL	$	POINTS	Visit	Visit Windows	Missed Visit Deduction
A	20	20	2 WEEK VISIT	±1 week	N/a
C	30	30	6 WEEK VISIT	±1 week	10
D	40	40	3 MONTH VISIT	±2 weeks	10
E	50	50	1 YEAR VISIT	±2 months	10
F	75	75	2 YEAR VISIT	±2 months	25
G	100	100	5 YEAR VISIT	±3 months	25
H	150	150	7 YEAR VISIT	±3 months	50
I	200	200	10 YEAR VISIT	±3 months	50

Please note that Level B was not included since this was only equivalent to $25 dollars. The interval points increase as the visit intervals occur further out from the date of surgery.

Missed Visits: If a patient has missed one or more visits, then the point value that equates to that patient's last completed visit is used as the base value. The visits that were missed are then deducted from that value using the "Missed Visit Deduction" column. See Scenario #5 for an example.

For example:
Scenario 1: A subject decides to withdraw after he/she has completed their 1-year visit and has stated he/she wants to use all of his/her "accrued" points for one gift.

- The patent would be provided with the Level E Book

Scenario 2: A subject decides to withdraw after he/she has completed their 1-year visit and has expressed that he/she would like to split his/her points into smaller gifts.

- The patient would be provided with a Level A (20) and Level C (30) book.

Scenario 3: A subject decides to withdraw after he/she has completed their 2-year visit and has expressed he/she would like to split his/her points into smaller gifts.

The patient could be provided with the following:

- The Level A (20) and the Level E (50) → the 5 remaining points would be forfeited

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- The Level C (30) and the Level D (40) → the 5 remaining points would be forfeited

It is important to note to the subject of their forfeit of these points if he/she chooses this redemption method. Please remind the subject that he/she can submit for a $75 gift to use all points.

Scenario 4: A subject decides to redeem his/her points at the 1-year visit and would still like to continue in the study.

- The subject would receive the Level E book for completing the 1-year visit. Once he/she reaches the 10-year visit, his/her points from the already redeemed 1-year visit would be deducted and the remainder available for prize redemption.

  10-year points 200 – 1-year points 50 = 150 points remain to redeem for gift

Scenario 5: A subject completes his/her 10-year visit but missed the following previous visits: 3 month and 5 year.

- The subject would receive the Level H book, which is worth 150 points. The patient would forfeit 15 points.
- The subject could receive any combination of booklets that did not exceed 165 points.

200 points (completing 10-year visit) – 35 points (see "missed visit column" in table above) = 165 points.

It is important to note to the subject that they may forfeit points depending upon which intervals they miss.

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