Orthopaedics

Triathlon Tritanium Cone Augments Outcomes Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments

Sponsor:	*Stryker Orthopaedics* *325 Corporate Drive* *Mahwah, NJ 07430* *201-831-5000*
Study Product:	*Triathlon Tritanium Cone Augments*
Protocol Number:	*76*
Clincaltrials.gov ID	*NCT02521103*
510(k) Clearance Number:	*K143393 – Triathlon Tritanium Cone Augments* *K190991 – Triathlon Tritanium Central Femoral Cone Augment*

Version 4.0

Date: 01 Aug 2024

CONFIDENTIAL

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Protocol Change History

Version	Description	Changed By
1	New	Danielle Campbell
2	Updated: • Study Synopsis: Inclusion / Exclusion Criteria (Exclusion Criteria E.); Study Duration; Number of Centers; Number of Cases • Section 1.3 - Clinical Data to Date • Section 2.2 - Number of Centers • Section 2.3 – Number of Subjects • Section 4.1 – Subject Recruitment and Screening • Section 4.3 – Early Withdrawal of Subjects • Section 8.4.2 – Sample Size Justification • Section 10 – Publication Plan • Section 13.3 - Subject Stipends or Payments	Christine Brozyniak
3	Updated: • Study Synopsis: Number of Cases; Study Device • Section 1.1 – Background • Section 1.2 – Preclinical Data • Section 2.3 – Number of Subjects • Section 3.1 – Study Device • Section 4.3 – Early Withdrawal of Subjects • Appendix A – FDA 510(k) Clearance Letters • Appendix B – Component Listing • Appendix I – Product Labeling	Ajay Rastogi

Version	Description	Changed By
4	Updated: • Study Synopsis – Objectives • Study Synopsis – Additional Data Collection • Study Synopsis – Number of Cases • Study Synopsis - Statistical Methodology • Study Synopsis - Evaluation Schedule- Radiographs: Bilateral AP Images clarification 6-10 Year column removed; Follow-Up Questionnaire requirement removed • Section 2.3 – Number of Subjects • Section 5.2- Radiographic Outcomes • Section 6.3.2- Device Retrieval Process • Section 8.1.3 – Exploratory Objective Analysis • Section 8.1.6 – Secondary Efficacy Analyses • Section 8.1.7 – Exploratory Efficacy Hypothesis • Section 8.1.8 – Exploratory Efficacy Analysis • Section 8.4.1 – Data Summary • Section 8.4.2 – Sample Size Justification • Appendix B – Component Listing • Appendix D – Model Informed Patient Consent • Appendix F- Retrieved Implant Analysis Protocol	Filesha Haniff

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List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
BMI	Body Mass Index
CFR	Code of Federal Regulations
CPTi	Commercially Pure Titanium
CSM	Clinical Study Manager
EC	Ethics Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
GCP	International Conference of Harmonisation Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HSS	Hospital for Special Surgery
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LEAS	Lower Extremity Activity Scale
PI	Principal Investigator
QOL	Quality of Life
ROM	Range of Motion
SAE	Serious Adverse Event
SC	Study Coordinator
SF-12	Short Form-12
TKA	Total Knee Arthroplasty
UADE	Unanticipated Adverse Device Effect
UHMWPE	Ultra High Molecular Weight Polyethylene

Study Synopsis

Title	A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments
Short Title	Triathlon Tritanium Cone Augments Outcomes Study
Protocol Number	76
Phase	Post-market
Methodology	This study is a prospective, open-label, post-market, non-randomized, multi-center clinical evaluation of the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments for revision total knee arthroplasty (TKA) in a consecutive series of patients who meet the eligibility criteria. The total enrollment goal for the study is a minimum of 145 cases, all of which will receive the Triathlon TS Total Knee System with at least one Triathlon Tritanium Cone Augment. The clinical outcomes of Triathlon Tritanium Cone Augments will be compared to published literature and data collected in the Triathlon TS Outcomes Study.
Study Duration	1. Follow-up of each revision TKA case to 5 years 2. Enrollment period of 48 months 3. Approximate 10-year total duration
Number of Centers	8 to 12 investigational centers
Hypothesis	The revision rate of the Triathlon Tritanium Cone Augments is expected to be less than 2.8% for aseptic loosening[1,2] of either the Femoral or the Tibial Cone Augments at 2 years postoperative.

Objectives	**Primary:** To evaluate the success rate of the Triathlon Tritanium Cone Augment with the Triathlon TS Total Knee System at 2 years postoperative, defined as absence of revision of the Femoral Cone Augment or Tibial Cone Augment for aseptic loosening. **Secondary**: • To evaluate unexpected end-of-stem pain with regards to the Triathlon Tritanium Cone Augments location and severity and compare to published literature[3] at 2 years postoperative. • To evaluate intraoperative bone defects using the Anderson Orthopaedic Research Institute (AORI) classification and correlate with the size and shape of cone implanted[6,7]. **Exploratory:** • To evaluate the mean KSS objective knee scores at 2 years postoperative for cases which received the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment.

Additional Data Collection	• Function and health related quality of life (QOL) will be compared between the Triathlon TS with Triathlon Tritanium Cone Augments and published results for other revision knee systems with metaphyseal augments, as well as the Triathlon TS Outcomes Study using the following outcomes measures:
	  ○ 2011 Knee Society Score (KSS)[9]
	  ○ Short Form-12 (SF-12)
	  ○ Lower Extremity Activity Scale (LEAS)
	  ○ Hospital for Special Surgery (HSS) Patella Score
	  ○ EuroQuol 5D (EQ-5D)
	  ○ Follow-Up Questionnaire
	• Data collected at 6-week, 6-month, 1-year, 2-year, and 5-year visits will be compared to above mentioned controls with respect to improvement from preoperative scores.
	• Radiographic stability, preoperative AORI classification and complications will be compared between those implanted with the Triathlon TS with Triathlon Tritanium Cone Augments and published results for other revision knee systems.
	• Surgical details will be compared to data collected as part of the Triathlon TS Outcomes Study.

Number of Cases	Cases will be enrolled until at least 145 cases have received the Triathlon TS Total Knee System with a Triathlon Tritanium Cone Augment. Additionally, between 40-50 cases (within the study population) will receive the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment.

Study Device	**Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments** Required Components : 1. Triathlon TS Femoral Component 2. Triathlon TS or Triathlon PS Tibial Insert 3. Triathlon TS Universal Tibial Baseplate 4. Triathlon TS Tibial Cone Augment and/or Triathlon TS Femoral Cone Augment (between 40-50 cases implanted with Triathlon TS Central Femoral Cone Augment) The femoral component and tibial baseplate must be used in a cemented application. The cone augments must be used in a cemented application with respect to the Triathlon TS Femoral and Tibial Components, and a cementless application with respect to the prepared bone. The subject's patellar component may or may not be revised based upon surgeon discretion. If revised, an X3 or N2Vac Triathlon Patellar Component must be used in a cemented application. Additionally, a variety of compatible Triathlon TS device accessories may be used, as indicated in the surgical protocol.

Inclusion/Exclusion Criteria	Inclusions: A. Patient has signed an IRB/EC approved, study specific Informed Patient Consent Form. B. Patient is a male or non-pregnant female, skeletally mature and age 18 years or older at time of study device implantation. C. Patient is a candidate for revision of all femoral and tibial components of a total knee replacement. D. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation. Exclusions: E. Patient has a Body Mass Index (BMI) > 45. F. Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation. G. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device. H. Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's disease) leading to progressive bone deterioration I. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days). J. Patient has a failed unicondylar knee prosthesis. K. Patient has a known sensitivity to device materials. L. Patient is a prisoner.

Statistical Methodology	**Primary Objective:** • 2-year success rate of the TS Total Knee System with Triathlon Tritanium Cone Augments with an endpoint of revision/removal of Femoral Cone Augment or Tibial Cone Augment for aseptic loosening will be compared with success of published literature on revision TKA with metaphyseal augments, with a 2.5% noninferiority margin. **Secondary Objectives:** • The unexpected end-of-stem pain at 2 years will be tabulated separately for cases with femoral cone implanted only, tibial cone implanted only, both femoral and tibial cone implanted. The two way tables will have the level of shin pain as row variable and level of thigh pain as column variable. • A two-way table of intraoperative AORI classification by femoral or tibial cone augment size will be presented. **Exploratory Objective:** • The mean of KSS Objective Knee Score at 2 years postoperative for cases receive the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment will be compared to 86 points with a 5 points noninferiority margin.

Evaluation Schedule

Evaluation	Preop X-rays (-1 yr) CRFs (-4 mos)	Intraop	6 weeks (± 2 wks)	6 months ((± 2 wks)	1 year (± 2 mos)	2 years (± 2 mos)	5 years (± 2 mos)
Inclusion/Exclusion	X						
Demographics & Medical History	X						
Preoperative Functional Evaluation	X						
Previous Implant Information		X					
Surgical Details		X					
Postoperative Functional Evaluation			X	X	X	X	X
SF-12	X		X	X	X	X	X
LEAS	X		X	X	X	X	X
HSS Patella Score	X		X	X	X	X	X
EQ-5D	X		X	X	X	X	X
Stem Tip Pain Diagram *If applicable	X*		X			X	X
Radiographs: 1. Bilateral* Anteroposterior (AP) X[a]. Long standing at pre-op and 6 weeks X[b]. Standard at 1 year, 2 years, and 5 years 2. Mediolateral (ML) 3. Merchant (30° flexion) **Bilateral AP x-rays are preferred. Unilateral AP x-rays may be submitted if bilateral images are not available.*	X[a]		X[a]	X[b]	X[b]	X[b]	X[b]

X: Evaluation is required for all cases.

Functional Evaluation: The Functional Evaluations include the 2011 KSS, a standardized instrument with both surgeon completed, and patient reported sections that evaluate function, satisfaction, pain and motion.

SF-12: The SF-12 is a 12-item patient questionnaire that evaluates general health and well-being.

LEAS: The LEAS is a self-administered patient evaluation designed to reflect patient activity.

HSS Patella Score: The HSS Patella Score incorporates both subjective symptoms and objective data specific to the patellofemoral joint.

EQ-5D: The EQ-5D is a standardized instrument that evaluates the patient's current health state.

Stem Tip Pain Diagram: The Stem Tip Pain Diagram is an anatomic diagram the patient completes to demonstrate the level and location of pain in their femur or tibia. This questionnaire is only applicable preoperative if the patient has a long stem previously implanted.

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 (GCP) Standards, associated Federal regulations and all applicable research requirements.

1.1 Background

Reconstruction of large metaphyseal defects, severe bone loss and achieving lasting component fixation in the femur or tibia during revision total knee arthroplasty (TKA) are clinically challenging problems[2,4]. Modern knee systems provide a modular approach to reestablishing the femoral and tibial anatomy, and implant selection should be based on the complexity of the reconstruction[5]. Various options are available for the management of small bone defects which include bone grafts, metal augments, and extended stems. To address larger defects categorized as Type II and Type III based on Anderson Orthopaedic Research Institute's (AORI) classification[6,7], metaphyseal cones or sleeves have shown to provide stable fixation and early structural support[4,8].

There have been a few studies showing early results for revision TKA using either tantalum cones or metaphyseal sleeves. In a retrospective study, Lachiewicz et al.[2] reported on 27 revision TKA procedures, including nine femoral cones and 24 tibial cones addressing Type IIB and III AORI bone defects. Overall there were two failures, one for infection and the second for aseptic loosening (3.7%) by 25 months post-op. All other cone augments showed evidence of osseointegration at the latest follow-up (average of 3.3 years). Additionally, Aggarwal et al.[1] retrospectively reviewed 104 revision TKAs in 103 patients needing metaphyseal sleeves. Of all the cases included in the analysis, two were revised for aseptic loosening at six months postoperatively. With an average follow-up of 43 months, the remaining 102 knees showed good evidence of osseointegration.

The Triathlon TS Total Knee System was developed as platform knee technology for Stryker Orthopaedics. The Triathlon TS Total Knee System, cleared for use under FDA 510(k) K070095 and K072221, includes femoral components fabricated from cast cobalt-chromium-molybdenum alloy, distal and posterior femoral augments, fluted stems, stem extenders, offset

adapters, tibial inserts fabricated from ultra-high molecular weight polyethylene (UHMWPE) and a patellar component also made from UHMWPE.

The first-generation Triathlon Tritanium Cone Augments, cleared for use under FDA 510(k) K#143393, have been developed to supplement the Triathlon TS Total Knee System, and are designed to accommodate voids of various sizes. The Triathlon Tritanium Central Femoral Cone Augments serve the same purpose and were created within a larger portfolio project as a contemporary and vertically integrated solution within the revision and oncology marketplace. They are cleared for use under FDA 510(k) K#190991. All components are compatible with the Triathlon TS Femoral Component, the Triathlon Universal Baseplate, the Triathlon TS Stems (cemented and cementless), the Triathlon TS augments and limited sizes of the Triathlon TS offset adapters as outlined in the surgical protocol.

1.2 Preclinical Data

The following bench tests (with test report numbers) were conducted with the Triathlon Tritanium Cone Augments:

Mechanical Properties (RD-14-075)
The following mechanical properties of the LRM-foam and the LRM-solid were tested to verify that the materials meet the pre-determined performance criteria.

- **Tensile Bond Strength (MTP 108.1-03):** The average tensile strength of the LRM-foam coating was 41.8 MPa.
- **Shear Bond Strength (MTP 109.1-03):** The average shear bond strength of the LRM-foam coating was 31.6 MPa.
- **Fatigue Strength (MTP 110.0-02):** Fatigue strength of the LRM-foam coating was 9.66 MPa at ten (10) million cycles.
- **Ultimate Tensile Strength and 0.2% Offset Yield Strength (MTP 114.0-05):** The average ultimate tensile strength of the LRM-solid substrate coupons was 67 ksi and the mean 0.2% offset yield was 50.3 ksi.
- **Rotating Beam Fatigue Strength (MTP 006):** The average fatigue strength of the LRM-solid substrate coupons was 30.66 ksi at ten (10) million cycles.

Materials Characterization (RD-14-076 and A0043790)

This testing effort characterized the physical properties of the modified surface of the three styles of cone augments. The modified surface, or porous coating, will interface with bone tissue or bone cement in the in-situ environment. The solid substrate for the device is also constructed of CPTi material made simultaneously with the LRM-foam by the LRM process. This solid substrate provides structural support for the device. In the in-situ environment, the inner surface of the device interfaces with the instrumentation for implantation and bone cement. The testing established that the porous coating meets the requirements outlined in the FDA guidance documents, “Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement”, April 28, 1994, and FDA Guidance Document, “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses, Guidance for Industry and FDA”, January 16, 2003. This surface is intended to provide biologic fixation.

Micromotion of Triathlon Cone Augment Constructs (RD-14-049 and RD-14-050 and A0040475)

Comparative testing was performed to evaluate the initial stability of the Triathlon Tibial and Femoral Cone constructs within the prepared simulated tibial cavity during a simulated stair descent activity and simulated femoral cavity during a normal walking profile. Data was compared to a predicate device, demonstrating that the Triathlon Cone Augments are at least equivalent to the predicate device in resisting micromotion.

Torque of Triathlon Cone Augment Constructs (RD-14-067 and A0043380)

Comparative testing was performed to evaluate the ability of the Triathlon Femoral Cone Augment to remain fixed to the tibial tray under clinically relevant loading. The test was completed with fixture of a 3D printed Stratasys Fused Disposition Modeling. All samples ran through the test cycle with no disassociation of the cone to the tibial baseplate. In all cases the test was stopped with the femoral rotation reached 30° which creates a torque which is beyond the capacity of the insert post. This is approximately three times the peak internal rotation experienced in the knee.

Additional testing was not needed for the Central Femoral Cone Augment. Analysis showed that the various stepped features and pockets, as well as the posterior and anterior cutout features,

provided torsional rigidity to the Central Femoral Cone Augment that was no worse than that of the first-generation Femoral Cone Augment.

Impaction of Triathlon Cone Augment Constructs (RD-14-013 and A0040158)

The strength of cone augment upon impaction into the joint was assessed to evaluate for any damage or deformation to the device. The cadaveric lab supported the cone augment strength via measurements of average force, speed, and energy applied.

The results of the bench top testing conducted for the Triathlon Tritanium Cone Augments identified acceptance criteria were met.

Copies of all test reports are available at Stryker Orthopaedics.

1.3 Clinical Data to Date

This study is the second Stryker sponsored multi-center prospective data collection on the Triathlon TS Total Knee System. This will be the first study collecting data on the Triathlon Tritanium Cone Augments. To date, early data from Clinical Protocol #65 Triathlon TS Outcomes Study has been presented at the following meetings. The abstracts are summarized below in **Table 1**.

Table 1. Publications from the Triathlon TS Outcomes Study

Title	Journal/ Conference	Authors	Summary
Anatomic Boss Position Decreases the Need for Offset in Revision Total Knee Arthroplasty	International Congress for Joint Reconstruction 2012 Southern Orthopaedic Association 2012	Hitt, Kirby; Stoker, Manoshi; Howard, Michael; Mittal, Yogesh and Heekin, David	Among 83 cases enrolled at 5 sites, 90.4% did not require a femoral offset; this is in contrast to previous reports that femoral offset adapters were needed in 55.4% of cases to achieve optimal joint line reconstruction. The authors concluded that the design of this system inherently reduced the need for use of the offset adapter in the majority of cases due to the anatomic boss position.
Recovery of Range of Motion, Pain and Function Similar in Revision and Primary Single Radius Knees	Eastern Orthopaedic Association 2013 International Society for Technology in Arthroplasty 2013	Stoker, Manoshi; Howard, Michael; Anthony, Danielle; Hitt, Kirby; Jacofsky, David and Smith, Eric	Clinical outcomes from two multicenter studies were analyzed to compare single radius designs: posterior stabilized primary TKAs and revision TKAs. Improvement was significantly higher in the revision group than the primary group, with comparable overall KSS scores in function and range of motion.The authors concluded that revision TKA subjects perform as well as primary TKA subjects with a single radius design.
Use of Augments Provides Greater Functional Outcomes than Augments with Offset Adapters	International Society for Technology in Arthroplasty 2013	Anthony, Danielle; Howard, Michael; Hitt, Kirby; Jacofsky, David; Smith, Eric and Orozco, Fabio	Of 125 cases collected in a multicenter study, only 17.6% of subjects received an offset adapter. Cases were divided into two groups: Group 1 with femoral and/or tibial augments only and Group 2 included subjects with femoral and or tibial augments and offset adapters. Early clinical outcomes show no difference in ROM, but greater improvements in overall KSS and PROMs in the augments only group. The authors concluded that the single radius design decreases the need for additional ancillary devices during revision TKA.
Reason For Revision Of Single Radius And Multi-Radius Total Knee Designs	Eastern Orthopaedic Association 2014	Smith, Eric; Hitt, Kirby; Orozco, Fabio; Campbell, Danielle and Robinson, Kristin	Among 177 revisions cases, reasons for revision were analyzed. Subjects we divided based on previous implant design: single radius (SR) TKA or multi-radius (MR) TKA. The SR group was primarily revised for Infection (23.7%), while the MR group was primarily revised for Global Instability (31.7%). Further differences between the two groups were noted in stability, with the MR group showing a higher incidence of instability >10mm in the AP plane and 10° in ML plane. The authors concluded that infection can be a result of improper healing and post-op care, while instability is also associated with component failures and malalignment.

Table 1. Publications from the Triathlon TS Outcomes Study (cont'd)

Title	Journal/ Conference	Authors	Summary
Joint Line Restoration in a Contemporary Revision Knee System	Journal of Knee Surgery 2015; 28(01): 075-082	Hitt, Kirby; Stoker, Manoshi; Howard, Michael; Mittal, Yogesh; Heekin, David and David Jacofsky	A new revision total knee arthroplasty device and associated instrumentation was investigated to determine if it could reduce intraoperative complexity and restore the joint line through the arc of motion. In a prospective multicenter study, a total of 95 consecutive patients undergoing a revision knee arthroplasty were evaluated. Medical history, functional health scores, and intraoperative data were collected. The joint line was restored to 28mm±5mm in full extension and 90° flexion. Significant improvements were noted in all functional and general health scores. The anatomic boss position may allow for a reduction in instrumentation, as the need for femoral offset adapters was limited. Joint line restoration with proper posterior condylar offset correlated with positive functional outcomes.
Use Of Tibial Augments Provides Improved Functional Outcomes In A Revision Single Radius Knee Design	World Arthroplasty Congress 2015	Smith, Eric; Della Valle, Craig; Mittal, Yogesh; Robinson, Kristin and Campbell, Danielle	Among 181 cases collected in a multi-center study, surgical details, clinical and patient-reported outcomes, and radiographic findings were evaluated in two groups based on whether a tibial augment was used (TA group) or not used (NA group). The study showed patients with tibial augments had less pain, better functional performance and improved stability at the 1- and 2-year follow-up visit.
Decreased Anterior Knee Pain with a Revision Single Radius Knee Design: Clinical Outcomes	World Arthroplasty Congress 2015	Hitt, Kirby; Della Valle, Craig; Jacofsky, David; Robinson, Kristin and Campbell, Danielle	Of 181 revision TKA cases studied, 98% of the subjects had a resurfaced patella, with only 40% of subjects having their patella revised. Objective and patient-reported outcomes including the Knee Society Score (KSS), Hospital for Special Surgery Patella Score (HSS) and radiographic findings were reviewed. The study shows significant increases in functionality and decreases in pain at the 6-week and 6-month timepoints, with further positive results to 2 years follow-up.
Revision Total Knee Arthroplasty: Do Postoperative Outcomes Vary Depending On The Etiology Of The Failed Arthroplasty?	World Arthroplasty Congress 2015	Smith, Eric; Hitt, Kirby; Orozco, Fabio; Robinson, Kristin and Campbell, Danielle	Reasons for revision were analyzed among the 181 cases in this revision TKA study. These included osteolysis, loosening, component failure, instability, component malpositioning, infection, and pain and/or stiffness. Subjects revised for pain or stiffness (pain/stiffness group) realized lower mean scores than the overall study population at 2 years postoperative and smaller score improvements from preoperative to postoperative on every measure analyzed except the KSS, which was in line with the overall group. In contrast, patients revised for infection (infection group) achieved greater improvement than the overall study population from preoperative to 2 years on the KSS, LEAS, and SF-36 Mental Component Score (MCS).

Table 1. Publications from the Triathlon TS Outcomes Study (cont'd)

Title	Journal/ Conference	Authors	Summary
Preoperative Activity Level Does Not Affect Postoperative Outcomes with a contemporary revision TKA	International Society for Technology in Arthroplasty 2016 American Academy of Hip and Knee Surgeons 2016 European Knee Society 2016	Hitt, Kirby; Della Valle, Craig; Campbell, Danielle and Brozyniak, Christine	Of the 181 cases in this revision study, subjects were divided into groups based on preoperative activity level using LEAS. Low activity had an LEAS score of 1-7 and High Activity has an LEAS score of 8-18. Postoperative improvement in both groups were similar in the KSS, but the LA group showed larger increases in the KSS Functional assessment at 6 weeks and 2 years. Higher SF-6D outcomes were also seen in the LA group at 1 year.
Ninety Day Readmission Rates in Revision Total Knee Arthroplasty	The European Federation of National Associations of Orthopaedics and Traumatology 2016 International Society for Technology in Arthroplasty 2016 European Knee Society 2016	Della Valle, Craig; Hitt, Kirby; Campbell, Danielle and Brozyniak, Christine	The readmission rate was 5% within 30 days and 9% within 90 days in a study population of 181 revision TKA cases. 16 readmissions involving 14 patients were reported within 90 days. More than half of the readmissions were related to an existing comorbidity or the index reason for revision and over one third of readmissions are medical in nature. Infection and wound healing complications represented more than half of the surgical complications.
Improved Clinical Outcomes Following Revision Total Knee Arthroplasty With or Without Patellar Revision	The European Federation of National Associations of Orthopaedics and Traumatology 2016	Hitt, Kirby; Smith, Eric; Della Valle, Craig; Robinson, Kristin and Campbell, Danielle	181 cases were analyzed for anterior knee functionality, pain after revision TKA and for review of outcomes associated with and without patella revision. The current study shows significant increases in functionality and decreases in pain at the six week and six month timepoints, with further positive results to two years. Early improvements may have been enhanced by the revision of a failing patellar component, although patients with retained patellar components display similar results to revised patients by one year postoperative. These improvements in anterior knee pain and function regardless of patellar revision suggest that a well fixed patellar component does not need to necessarily be revised to alleviate symptoms.

Table 1. Publications from the Triathlon TS Outcomes Study (cont'd)

Title	Journal/ Conference	Authors	Summary
Improved Health Related Quality of Life and Clinical Outcomes Using A Contemporary Revision Total Knee System	The European Federation of National Associations of Orthopaedics and Traumatology 2016	Hitt, Kirby; Smith, Eric; Della Valle, Craig; Campbell, Danielle and Robinson, Kristin	Of the study population of 181 cases, the majority consisted of primarily first-time revision patients (81.2%) with a diagnosis of osteoarthritis. Clinically significant results were seen in the LEAS, with the average score improving by 1.6 points and 1.9 points at six months and two years, respectively. SF-6D scores indicated moderate clinical relevance at each postoperative timepoint, with an effect size of 0.65, 0.70, and 0.69 at six months, one year, and two years, respectively. The KSS Pain/Motion and Functional Scores were determined to be highly correlated with the SF-6D scores (Pearson's r > 0.6) at one and two years postoperatively.

2 Clinical Study Plan

2.1 Study Design

A prospective, post-market, multi-center design will be employed. Radiographs will be assessed by an independent reviewer.

2.2 Study Centers

Cases will be enrolled at eight to twelve centers. For investigators that have not used the Triathlon TS Total Knee System previously, enrollment of cases into the study will commence when each investigator has completed a learning curve of three cases using the Triathlon TS device. The enrollment goal is approximately 25 cases per investigator utilizing the Triathlon Tritanium Cone Augments but will vary dependent upon the number of participating centers. Although a goal is presented, there is no maximum limit to the number of cases that a center may enroll. In the event that a center far exceeds the enrollment goal, Stryker may ask the center to cease enrollment so as not to skew the data. All participating centers will comply with the federal regulations regarding patient informed consent and Institutional Review Board (IRB) or Ethics Committee (EC) approval. Non-compliance of a study center may result in termination of the center's participation in the study.

2.3 Number of Subjects

Cases will be enrolled until at least 145 cases have received the Triathlon TS Total Knee System with a Triathlon Tritanium Cone Augment. Additionally, between 40 - 50 cases (within the study population) must receive the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment.

3 Device Description

3.1 Study Device

All cases in this post-market study will receive a femoral or tibial Triathlon Tritanium Cone Augment. The Triathlon Tritanium Tibial and Femoral Cone Augments were cleared for use in the United States under FDA 510(k) K#143393 on January 13, 2015. The Triathlon Tritanium Central Femoral Cone Augment was cleared for use in the United States under FDA 510(k) K#190991 on August 15, 2019. See Appendix A for the FDA clearance letter.

The Triathlon Tritanium Cone Augments are an extension of the Triathlon TS system, intended to be used as an optional accessory component in primary or revision TKA. The Triathlon Tritanium Cone Augments are comprised of commercially pure titanium (CPTi) with the outer surface incorporating a foam porous coating. The Triathlon Tritanium Cone Augments are designed to accommodate voids of various sizes. The components may be placed with or without bone cement into the prepared bone, but will be used in a cemented application with respect to the Triathlon TS femoral and tibial components. The components are compatible with the Triathlon TS femoral components, the Triathlon Universal Baseplate, limited sizes of the Triathlon TS Stems (cemented and cementless), the Triathlon TS augments, and limited sizes of the Triathlon TS offset adapters.

There are four designs of Triathlon Tritanium Cone Augments:

- Femoral Cone Augments
- Central Femoral Cone Augments
- Symmetric Tibial Cone Augments
- Asymmetric Tibial Cone Augments

The Femoral Cone Augment (**Figure 1**) is available in six sizes (Size 1-2, Size 3, 4, 5, 6 and Size 7-8), in left and right configurations. The Femoral Cone Augments are intended to be cemented to the internal aspect of the appropriate Triathlon TS femoral component. Previously available distal and/or posterior femoral augments may be utilized, as the femoral cone is cemented to the femoral component/augment combination. The femoral cone is open on the anterior surface to accommodate the TS intercondylar box, any anterior bone that is present, and any stems/stem extenders that are intended to be used. The internal aspect of the cone augment has normalizations for bone cement bonding, and has a keyed feature to allow the use of an impactor during insertion. The outer surface of the femoral cone incorporates a CPTi foam porous coating that is designed for biological fixation in cementless applications, or for cement interdigitation in cemented applications, as well as solid areas without coating. The Femoral Cone Augment is intended to be used to provide support and fill bone voids in the metaphyseal region of the distal femur.

Figure 1. Femoral Cone Augment

The Central Femoral Cone Augment (**Figure 2**) is an extension of the first-generation Femoral Cone Augment and is available in five sizes (Size 1-2, 3-4, 5, 6, and 7-8), in left and right configurations. This cone also accommodates the TS intercondylar box, and a CPTi porous outer surface for biological fixation, or interdigitation with bone cement. This design of the femoral cone is compatible with the same devices as the first-generation Femoral Cone Augment and is implanted in the same manner.

Figure 2. Central Femoral Cone Augment

The Symmetric Tibial Cone Augment (**Figure 3**) is intended to be used with the Triathlon Universal baseplate and will accommodate the use of previously available tibial augments. The tibial cones are cemented to the Universal baseplate. The Symmetric Tibial Cone Augment is available in five sizes (A – E). This design features a cone shaped geometry tapering from the surface nearest the joint line to a smaller dimension distally. The narrow end of the cone provides an opening with a minimum dimension to allow for the use of compatible Triathlon TS stems. Offset adapters may also be used. There is a keyed feature present on the superior aspect of the cone to allow for the use of an impactor. The internal surface of the cone contains normalizations for cement bonding. The outer surface of cone incorporates a CPTi foam porous coating that is designed for biological fixation in cementless applications, or for cement interdigitation in cemented applications. The Symmetric Cone Augment is intended to be used to provide support and fill bone voids in the metaphyseal area of the tibia.

Figure 3. Symmetric Tibial Cone Augment

The Asymmetric Tibial Cone Augment (**Figure 4**) is available in four sizes (B, C, D, and E) with right medial/left lateral, and left medial/right lateral options. This design features a lobe at the superior aspect of the cone to fill asymmetric bone voids in the tibial metaphysis. This cone also features an internal surface with normalizations for cement interdigitation, and a CPTi porous outer surface for biological fixation, or interdigitation with bone cement. This design of tibial cone is compatible with the same devices as the Symmetric Tibial Cone and is implanted in the same manner.

Figure 4. Asymmetric Tibial Cone Augment

The following Triathlon Tritanium Cone Augment catalog numbers are permissible according to this study protocol and are in the following format, where 'XX' varies by size:

5549-A-3XX (Femoral Cone Augment)

5549-A-6XX (Central Femoral Cone Augment)

5549-A-1XX (Symmetric Tibial Cone Augment)

5549-A-2XX (Asymmetric Tibial Cone Augment)

The full listing of permissible Triathlon Tritanium Cone Augment catalog numbers may be found in Appendix B.

3.2 Additional Devices

Additionally, only the following **Stryker compatible** devices may be used, according to this study protocol:

Required Additional Components	
5512-F-XXX	Triathlon TS Femoral Component
5521-B-XXX	Triathlon TS Universal Tibial Baseplate

Study Specific Tibial Inserts	
5537-G-XXX	Triathlon TS Tibial Insert
5532-G-XXX	Triathlon PS Tibial Insert, X3
5532-P-XXX	Triathlon PS Tibial Insert, N2Vac

Optional Ancillary Devices		
5550-G-XXX	Triathlon Patellar Component, Symmetric	X3
5550-L-XXX		N2Vac
5551-G-XXX	Triathlon Patellar Component, Asymmetric	X3
5551-L-XXX		N2Vac
5565-S-XXX	Triathlon Fluted Stem	100 mm
5566-S-XXX		150 mm
5560-S-XXX	Triathlon Cemented Stem	
5571-S-XXX	Triathlon Stem Extender	

5570-S-XXX	Triathlon TS Offset Adapter	
5540-A-XXX	Triathlon Femoral Distal Augment	5 mm
5541-A-XXX		10 mm
5542-A-XXX		15 mm
5543-A-XXX	Triathlon Femoral Posterior Augment	5 mm
5544-A-XXX		10 mm
5545-A-XXX	Triathlon Tibial Half Block Augment	5 mm
5546-A-XXX		10 mm
5540-A-000	Triathlon Femoral Augment Locking Screw	
5545-A-000		

The compatible Stryker components are listed in the surgical protocol and Appendix B.

In the case of any uncertainty regarding device compatibility, the current version of the Triathlon TS surgical protocol should be reviewed.

4 Study Procedures

4.1 Subject Recruitment and Screening

Patients will be recruited at the study centers during preoperative visits through normal referral patterns. Advertising for the study at each center will be at the discretion of the investigator. All handouts, brochures, advertisements, etc. must be approved by the IRB/EC prior to the dissemination of any recruitment materials to potential subjects. Study advertisement content may be found in Appendix C.

During the preoperative visit, patients that are possible candidates for this study will be screened to determine if they meet the inclusion/exclusion criteria. If the patient is a candidate, the investigator will propose participation in the study to the patient, according to GCP guidelines. Patients must sign an IRB/EC approved Informed Patient Consent Form prior to participation in the study, as well as prior to any data collection.

4.2 Patient Informed Consent and Guidelines

All patients for this study will be provided an Informed Patient Consent Form describing this study and providing sufficient information for them to make an informed decision about their participation. The Informed Patient Consent Form 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. For international sites, the applicable country regulations are required. See Appendix D for a copy of the Model Informed Patient Consent. This will be submitted with the protocol for review and approval by the IRB/EC for the study. All patients must provide written consent after having had adequate time to consider their participation in the study. The formal consent of a patient, using the IRB/EC approved Informed Patient Consent Form, must be obtained before that patient is submitted to any protocol related procedures that are not part of normal care. Written documentation of consent must be provided on the Informed Patient Consent Form'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 Informed Patient Consent Form. The patient or his/her legal representative should receive a signed copy of the Informed Patient Consent Form, according to GCP guidelines.

The procedure for obtaining informed consent is outlined below:

- Use a current IRB/EC approved copy of the Informed Patient Consent Form.
- Review thoroughly with the patient, allowing adequate time to consider participation in the study and ask questions, before having them sign.
- After the patient has consented to the procedures, ensure he/she signs and dates the Informed Patient Consent Form.
- The person obtaining consent also signs and dates the signature page.
- Provide a copy of the Informed Patient Consent Form to the patient.
- If required, provide the hospital with a copy of the signed Informed Patient Consent Form.
- Maintain the signed original in the patient's study chart.

4.3 Early Withdrawal of Subjects

When and How to Withdraw Subjects

In the event that the subject is discontinued by the investigative center prior to the final study evaluation, the subject will be notified by the center that he/she is no longer in the study and a Study Termination eCRF will be completed.

The following is a list of reasons for which subjects may be withdrawn and the date of termination that should be used on the Study Termination eCRF in each situation. This list is not all inclusive:

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

At the time of study surgery it is required that the following components are implanted to be included in the analysis:

- Triathlon Tritanium Femoral Cone Augment or Central Femoral Cone Augment and/or Tibial Cone Augment
- Triathlon TS Femoral Component
- Triathlon TS Universal Tibial Baseplate
- Triathlon TS Tibial Insert or Triathlon PS Tibial Insert

Revision or removal of the Triathlon Tritanium Cone Augments for aseptic loosening constitutes a failure. Revision or removal of all implanted Triathlon Tritanium Cone Augments for any reason requires study termination for the subject.

If revision of the Tibial Insert or the Patellar Component is required during the study, the event does not constitute a failure or study termination.

Patellar component revision at the time of study surgery is optional. However, if the subject requires patellar component revision a Triathlon Patellar Component must be used. If the patellar component is not revised at the time of study surgery and is later revised, it must be revised to a Triathlon Patellar Component. This event is considered a reoperation and does not constitute a failure or study termination.

If the subject fails to return for his/her 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 eCRF will be completed **only after notifying Stryker of the subject's status** and **being given approval to terminate**.

In the event a subject does not have surgery, Stryker should be contacted to discuss if/when the surgery will be rescheduled. If the surgery is rescheduled more than 4 months from the date of consent, the subject will need to reaffirm participation in the study. All preoperative data will need to be re-collected to be current within 4 months of study surgery. If the surgery is not to be rescheduled or if the subject is no longer considered an appropriate study candidate, a Study Termination eCRF may be completed **only after notifying Stryker of the subject's status** and **being given approval to terminate**.

When a subject completes the study according to protocol, including the final study evaluation, a Study Termination eCRF will be completed.

5 Study Details

5.1 Study Objectives and Evaluation Schedule

The primary and secondary study objectives, as well as additional data collection are listed on page 2. For the evaluation schedule, please reference page 7.

5.2 Radiographic Outcomes

Radiographs will be taken and collected in the anteroposterior (AP), mediolateral (ML), and merchant or skyline views for the preoperative, 6-week, 6-month, 1-year, 2-year, and 5-year intervals. At the preoperative and 6-week follow-up, a long-standing AP view will be taken. The suggested radiographic technique for the views required is included in Appendix E.

Radiographs will be evaluated by an independent reviewer throughout the course of the study. Parameters for radiographic failures will follow the guidelines that have been set by the Knee Society[10]. Radiographic analysis of the tibial component will employ nine zones (Zone 1 – Zone 9) in the AP view and seven zones (Zone 1 – Zone 7) in the lateral view. Radiographic analysis of the femoral component will employ five zones (Zone 1 - Zone 5) in the AP view and nine zones (Zone 1 – Zone 9) in the lateral view. Several parameters will be reviewed by zone, including mechanical alignment, radiolucency, and osteolysis and migration.. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width is defined as radiolucency present. Cases that present with at least 2 mm radiolucency in all zones within a single view will be considered radiographic failures. A migrating or shifting prosthesis with or without disappearance of

radiolucent lines or bone-prosthesis or bone-cement interface may be considered as a possible radiographic failure. This determination will be made by the independent reviewer.

6 Adverse Events

6.1 Reporting of Adverse Events

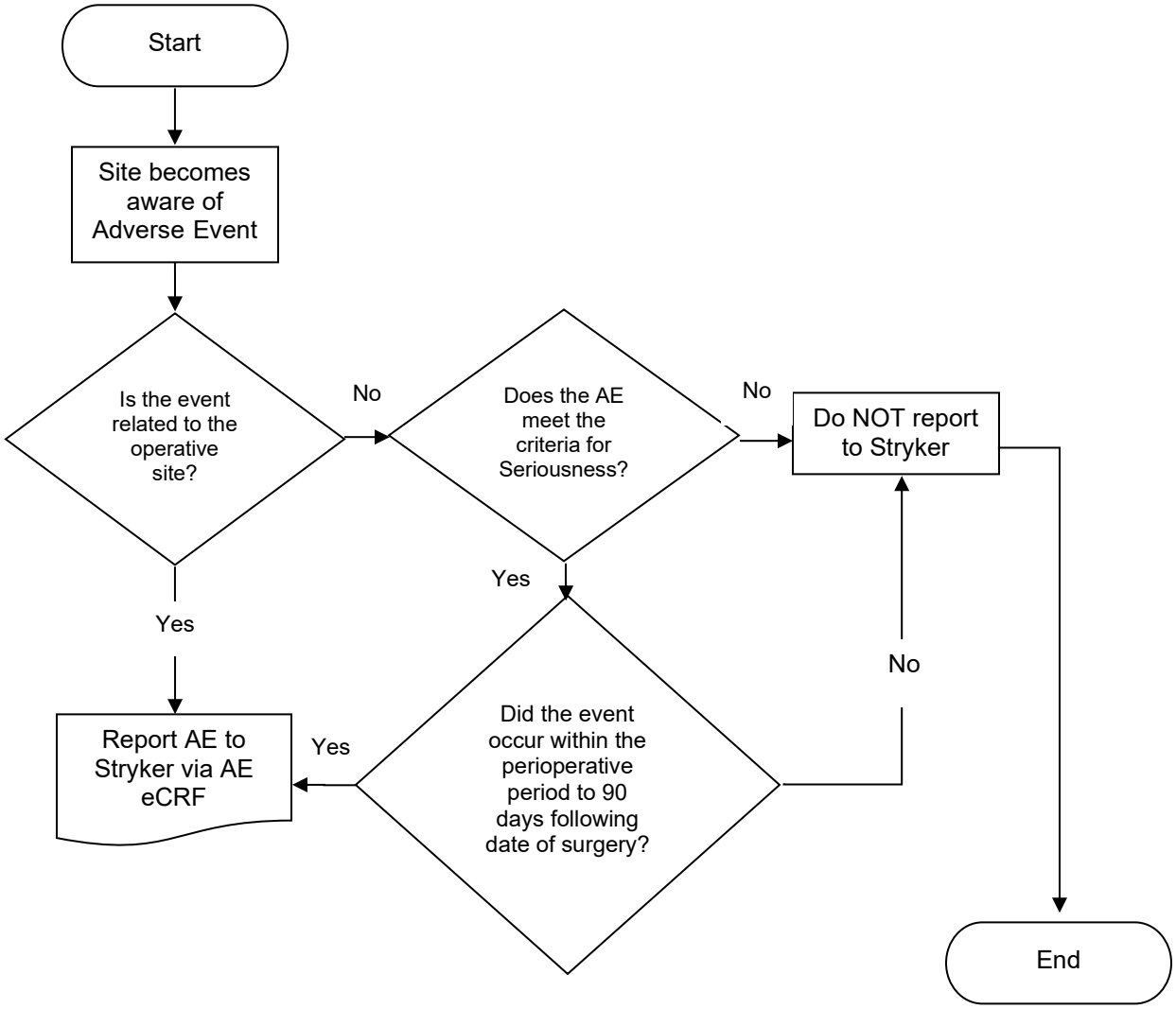
The AE reporting requirements for this study are as follows:

- All AEs that meet the definition of serious (see page 27) and occur within the perioperative period (intraoperative to hospital discharge) to 90 days following the date of surgery.
- All AEs related to the operative site, regardless of seriousness or time of occurrence.

On postoperative functional evaluations, investigators and SCs will be prompted to question subjects as to whether they have seen a doctor for any reason, been hospitalized for any reason or have a current impediment to their function.

The following decision tree facilitates identification of AEs for which reporting is required under this study protocol:

Figure 5. Adverse Event Decision Tree



General Physical Examination Findings

At screening for inclusion into the study, any clinically significant abnormality should be recorded as a preexisting condition and reported on the Demographics eCRF. From the time of consent forward, any new clinically significant findings or abnormalities that meet the definition of a protocol defined AE must also be recorded and documented as an AE.

Adverse Event Reporting Period

The study period during which AEs 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. The start of study procedures is considered to be the point of consent. Any AEs which fit the protocol defined reportable events must be reported from the time of consent until study completion.

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

All operative site events occurring at any time as well as all serious adverse events (SAEs) occurring within 90 days postoperative will be collected and compared to published data. It is expected that the AE rates reported for the Triathlon Tritanium Cone Augments will be comparable to those reported in the literature for other revision TKA systems on the market.

6.2 General Adverse Event Definitions

Following is a list of general AE definitions. For the purposes of this study, only SAEs occurring within 90 days postoperative, excluding elective procedures, as well as all AEs related to the operative site should be reported.

Adverse Event

An **AE** is any untoward medical occurrence in a clinical investigation subject, which changes the medical baseline of the subject. An AE 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). See Section 6.1, Reporting of Adverse Events, for the AE reporting requirements for this study.

Anticipated Adverse Event

An **anticipated AE** is an AE, of which the nature, severity or degree of incidence is known and identified in applicable product labeling, published literature or the study protocol. The list of anticipated events is provided in Section 11, Risk/Benefit Assessment.

Serious Adverse Event

A **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

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.

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 is 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.

6.3 Study Sponsor Notification by Investigator

Of reportable AEs, certain events must be submitted to Stryker within 24 hours for timely notification:

Adverse events that require time sensitive reporting:

An adverse event should be reported to Stryker Clinical Research either by telephone/fax/email within 24 hours of the site becoming aware of the event if any of the following apply:

- The AE occurs intraoperatively or is related to the surgical procedure.
- The AE is considered by the investigator to be device related or if the investigator is uncertain regarding the device related assessment;
- The AE required a reoperation of the study knee or a revision of any study knee components.

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 study treatment was discontinued • Investigator assessment of the association between the event and the study treatment

These reports will be evaluated by Stryker to determine if a Product Inquiry (PI) is required.

It is recommended that all other reportable AEs are submitted through eCRF entry within 2 weeks.

6.3.1 Ethics Committee/Institutional Review Board Notification by Investigator

Reports of AEs (including follow-up information) must be submitted to the EC or IRB according to their specific requirements. Copies of each report and documentation of EC/IRB notification and receipt will be kept with the investigator's study files.

6.3.2 Device Retrieval Process

If the study device is removed for any reason, Stryker Orthopaedics will retrieve the Triathlon TS system for analysis to help characterize potential device-related

complications. In the event that any portion of the Triathlon TS Total Knee System is removed from a study subject, the procedure outlined in the Retrieved Implant Analysis Protocol (Appendix F) should be followed, as allowed by the hospital and institution. When revision of a study subject is scheduled, the study coordinator (SC) should contact the Clinical Study Manager (CSM) or other Stryker Clinical Research personnel assigned to the project, as soon as possible.

6.4 Recording of Adverse Events

All protocol defined AEs occurring during the study period must be recorded; this includes events that occur between visit intervals. The clinical course of each event should be followed until resolution or stabilization.

6.5 Medical Monitoring

It is the responsibility of the investigator to oversee the safety of the study at his/her center. This safety monitoring will include careful assessment and appropriate reporting of AEs, as previously noted. Stryker will conduct formal investigations via the Product Surveillance Department of those AEs which are submitted through our Product Inquiry System.

7 Data Management

7.1 Database

Data will be collected at each center and entered into Stryker's Electronic Data Capture (EDC) system. The system can be accessed remotely by each investigative center and the data entered will be managed by Stryker. Subject data will be processed and monitored according to the protocol schedule by Stryker or Stryker representatives. Draft specifications to support eCRFs are provided in Appendix G and patient questionnaires are provided in Appendix H.

7.2 Confidentiality

This study will comply with the 2002 HIPAA privacy rule. As such, Stryker will only collect that information which is necessary to support the objectives of the clinical study. Stryker will take precautions to ensure that data received is as de-identified as possible. In the case that some identified information is received, Stryker will ensure that any identifying information is not reported. Study subjects will authorize Stryker to use their health information in support of the clinical study during the informed consent process. Should a subject choose to withdraw

authorization, Stryker may use data collected prior to the withdrawal of authorization in order to maintain data integrity.

7.3 Source Documents

Source data include all information, original records of clinical findings, observations or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents. Examples of these original documents and data records include: hospital records, clinical and office charts, study worksheets, laboratory notes, memoranda, subject questionnaires, pharmacy dispensing records, recorded data from automated instruments, radiographs, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical study.

All data points collected during preoperative and follow-up visits must be documented in the subject's chart. This includes range of motion values, pain and function as well as AEs and additional comments. The informed consent process should also be documented in the patient chart. Monitors, defined further in Section 9, will be comparing the eCRFs against source documents for adequacy. The monitors will seek to draw a reference between each data point on the eCRF and the subject's chart. Thus, one cannot derive pain, ROM or function based on a chart note that reads "Patient doing well." Every effort should be made to ensure complete source documentation.

Centers are required to create a source documentation plan including any applicable source documentation worksheets prior to enrollment.

7.4 Electronic Case Report Forms

The study eCRFs are the primary data collection instrument for the study. All data requested on the eCRF must be documented. All missing data must be explained. It is recommended that eCRFs be completed and electronically signed by the investigator within 2 weeks of the evaluation date.

7.5 Data Clarification Requests

If errors or omissions are noted by Stryker upon review of the data entered into the eCRFs, a query will be sent to the center within the EDC system. Queries should be answered in a clear and comprehensible manner. If the query requires a change to study data, the EDC system will update the eCRF automatically with the data captured in the query response. The investigative center will be required to reapply their electronic signature to the modified eCRF. Modified eCRFs need not be printed and included in conjunction to answered queries.

7.6 Protocol Deviations

Any major deviation from this protocol will be recorded in Stryker's Clinical Trial Management System and must be reported to the EC/IRB by the investigational site 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
- Visit deviations, including:
    - Unavailable primary endpoint

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

7.7 Records Retention

It is the investigator's responsibility to retain study essential documents for 2 years after the date of the final report, or 2 years after the date of investigative center termination. These documents should be retained for a longer period if required by an agreement with Stryker.

8 Statistical Plan

8.1 Study Objectives

8.1.1 Primary Objective Analysis

The primary efficacy parameter is the revision/removal of femoral cone augment or tibial cone augment for aseptic loosening at 2 years postoperative.

8.1.2 Secondary Objective Analyses

The secondary efficacy parameters include:

- The end-of-stem pain – shin pain and thigh pain at 2 years
- The intraoperative AORI classification, size, and shape of the femoral or tibial cone augment

8.1.3 Exploratory Objective Analysis

The exploratory efficacy parameter is the KSS objective knee score at 2 years postoperative for cases which received the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment.

8.1.4 Primary Efficacy Hypothesis

The primary hypothesis to be tested will be that the success rate at 2 years postoperative with the Triathlon Tritanium Cone Augments is not worse than 97.2% with a non-inferiority margin of 2.5%. That is, the following hypothesis will be tested:

H_0: Pt <= 97.2% - 2.5% H_A: Pt > 97.2%- 2.5%

Here, Pt is the success rate at 2 years postoperative with the Triathlon Tritanium Cone Augments. A case success at 2 years is defined as no incidence of revision/removal of femoral or tibial cone augment for aseptic loosening within 2 years.

8.1.5 Primary Efficacy Analysis

A 90% two-sided confidence interval will be computed for the success rate at 2 years. If the lower bound of the confidence interval is greater than 94.7%, then the non-inferiority hypothesis will be supported; that is the 2 year success rate is non-inferior to 97.2% with a margin of 2.5%. If the lower bound of the confidence interval is greater than 97.2% then it is supported that the 2 year success rate is superior to 97.2%.

The Kaplan-Meier survival curve of revision/removal of femoral or tibial cone augment will be displayed using SAS/PROC LIFETEST.

8.1.6 Secondary Efficacy Analyses

A two by two table of shin pain by thigh pain at 2 years will be created separately for cases with femoral cone augment implanted only; tibial cone augment implanted only; and both femoral cone augment and tibial cone augment implanted.

The intraoperative AORI classification and the size of the femoral or tibial cone augment will be tabulated.

8.1.7 Exploratory Efficacy Hypothesis

For cases which received the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment, the exploratory hypothesis to be tested will be that the mean of KSS Objective Knee Score at 2 years postoperative is no worse than 86 with a non-inferiority margin of 5. The performance goal for 2-year KSS Objective Knee Score was calculated as 86 - 5 to give 81. That is, the following hypothesis will be tested:

H_{01}: u <=81 H_{A1}: u >81

Here, u is the mean KSS Objective Knee Score at 2 years postoperative.

8.1.8 Exploratory Efficacy Analysis

For cases which received the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment, A 95% two-sided confidence interval for the mean of KSS Objective Knee Score at 2 years will be computed. If the lower bound of the confidence interval is greater than 81, then it is supported that KSS Objective Knee Score at 2 years is no worse than 86 with a non-inferiority margin of 5. If the lower bound of the confidence interval is greater than 86, then it is supported that KSS Objective Knee Score at 2 years is better than 86.

The analysis for the additional data collection is in 8.4.1 Data Summary.

8.2 Safety

8.2.1 Safety Parameters

Safety parameters include all protocol-defined adverse events as well as revision and/or removal rates. For details regarding protocol-defined adverse events, see Section 6.1.

8.2.2 Safety Analyses

The frequency and percentage of all protocol-defined adverse events will be tabulated.

The all cause revision/removal rates for the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments will be calculated.

The Kaplan-Meier survival curve of all cause revision/removal will be displayed using SAS/PROC LIFETEST.

For details regarding protocol-defined adverse events, see Section 6.1.

8.3 Missing Data

No missing data will be imputed.

8.4 Statistical Methodology

8.4.1 Data Summary

Descriptive statistics will be computed for all baseline conditions and demographic parameters. That is, for continuous data, the N, mean, median, standard deviation, minimum and maximum will be computed. For categorical data, the frequency will be computed. The data will be presented by appropriate subgroups (e.g., center).

For all additional data collected that are not required for direct support of a study objective, data will be summarized according to visit. For parameters represented by continuous variables (e.g., ROM), the summaries will consist of the N, mean, median, standard deviation, minimum, and maximum values. For categorical variables (e.g.,gender), the frequency and percentage in each category will be presented.

A two way table of preoperative AORI classification by femoral or tibial cone augment size will be presented.

A table of shin pain by thigh pain will be created separately for cases with femoral cone augment implanted only, tibial cone augment implanted only, and both femoral cone augment and tibial cone augment implanted at preoperative, 6 weeks, 2 years, and 5 years.

LEAS at 2 years will be compared to the Triathlon TS Outcomes Study as reported at 2 years postoperative, adjusted by preoperative LEAS, age, gender, and BMI, if applicable. The improvement from preoperative visit to postoperative visits will be compared with the Triathlon TS Outcomes Study, if applicable.

The HSS Patella Score at 2 years postoperative will be compared to the Triathlon TS Outcomes Study as reported at 2 years postoperative, adjusted by preoperative HSS Patella Score, age, gender, and BMI, if applicable. The improvement from preoperative visit to postoperative visits will be compared with the Triathlon TS Outcomes Study if applicable.

Statistical analyses including T-test, Wilcoxon test or Chi-square tests will be utilized for comparing the applicable surgical data collected from Triathlon TS Outcomes Study.

For radiographic data, data will be presented according to visits for available parameters. Frequency and percentage will be computed for radiolucency according to visit. Lists will be generated for migration over time. Radiographic failure will be evaluated, where radiographic failure is defined as at least 2 mm radiolucency in all zones within a single view. Radiographic failure due to device migration will be evaluated by the independent reviewer. Documentation of statistical analyses utilizing SAS® software version 9.1.3 or higher.

8.4.2 Sample Size Justification

For primary efficacy objective, based on the literature review[1,2], it is reasonable to have a reference value of 97.2% for success rate at 2 years. A case success at 2 years is defined as no incidence of revision/removal of femoral or tibial cone augment for aseptic loosening within 2 years.

Based on Triathlon TS Outcome Study, it is reasonable to assume the expected success rate at 2 years is 98.8%, 100 cases will be needed to have a power of 80% to detect that the 2 year success rate is non-inferior to 97.2% with a margin of 2.5% at 5% significance level. After factoring a 30% lost to follow-up rate, a total of 145 cases will be needed.

For exploratory efficacy objective among cases receive the Triathlon TS Total Knee System with a Triathlon Tritanium Central Femoral Cone Augment, based on the existing data of this study for non-femoral central cone, it is reasonable to have a reference value of 86 for the mean of KSS Objective Knee Score at 2 years postoperative, with a standard deviation of 10, 32 cases will be needed to have a power of 80% to identify the mean of KSS Objective Knee Score at 2 years postoperative is Non-Inferior to 86 with a non-inferiority margin of 5 at 2.5% significance level. After factoring a 30% attrition rate, a total of 46 cases will be needed.

8.4.3 Interim Analyses

No interim analysis is planned.

8.4.4 Analysis Population

Per Protocol Population: The study population for analysis will include all non-censored subjects who receive a Triathlon TS with Triathlon Tritanium Cone Augment and are available for efficacy evaluation at the 2-year primary endpoint. The primary and secondary efficacy analyses will be based on the per protocol population.

Safety Population: The safety population will include all non-censored subjects who received Triathlon TS with Triathlon Tritanium Cone Augment. The safety analysis will be based on the safety population.

9 Study Monitoring, Auditing, and Inspecting

9.1 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 studies 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.

Each investigational site conducting this study will be monitored at least once per year, with additional monitoring 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, as applicable, and has adequate space to conduct the monitoring visit, when applicable. The monitor will review all source documents and compare them to the data contained in the eCRFs, in addition to performing a periodic review of regulatory documents such as EC/IRB approvals. The monitors will need the following:

- An area where they can review study data, when monitoring is conducted on site
- Access to eCRF data for all cases
- Access to source documentation
- Regulatory documents
- Time to discuss findings with the SC and the investigator

9.2 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 must 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 EC/IRB, Stryker and/or government regulatory bodies of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data). The investigator will ensure the capability for inspections of applicable study-related facilities.

10 Publication Plan

It is anticipated that publication of the multi-center study results will be compiled and submitted to a peer-reviewed journal at the time the study cohort reaches 2 years and 5 years of follow-up. Early results with regard to surgical information and postoperative biomechanics may be published prior to the 2-year time point. Additional publication proposals may also be made by investigators at any time and will be considered.

This study will utilize the guidelines for authorship published by the International Committee of Medical Journal Editors (ICMJE). This guidance can be referenced at www.icmje.org.

At the completion of the study, each participating study investigator shall have independent publication privileges for his/her own center's results. These manuscripts and abstracts will be delayed until after the 2- and 5-year multi-center publications are submitted. Although Stryker will not be involved in coordinating these independent manuscripts, 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, that no off-label use of Stryker devices is promoted and that the data is accurately represented. Any publications resulting from this study must be submitted to Stryker for review at least 60 days prior to submission of publication.

11 Risk/Benefit Assessment

11.1 *Risk Category*

There are no additional risks associated with participating in this study over and above that of the revision TKA procedure.

11.2 Potential Risk

The study involves the routine assessment of a revision TKA procedure. The Triathlon Tritanium Cone Augments have been cleared for use by the FDA and will be used according to their labeling, included in Appendix I. Assessment involves questionnaires, patient and physician assessments as well as routine radiographs. The information collected will be kept confidential and will comply with the HIPAA privacy rule.

While the expected life of TKA 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 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 of normal healthy bone.

Adverse effects associated with revision TKA include the following:

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

With all implanted devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of metal and UHMWPE. Particulate is generated by interaction between components as well as adhesion, abrasion and fatigue. Secondarily, particulates can be generated by third body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Early and late loosening of total knee components can occur. Early biomechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis 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.

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

Intraoperative fissure, fracture, or perforation of the femur or tibia can occur due to impaction of the component into the prepared femur or tibia. Postoperative femoral or tibial fracture can occur due to trauma, the presence of defects or poor bone stock.
Metal sensitivity reactions have been reported following joint replacement.

AEs may necessitate reoperation, revision, arthrodesis of the involved joint, or amputation of the limb.

11.3 *Expected Complications and Rates of Occurrences*

Complications associated with TKA procedures, such as those performed with the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments, have been reported. These include the potential for: injury to the knee's neurovascular structures, loosening of the components, heterotopic bone formation, infection, deep vein thrombosis, pulmonary embolism, metal sensitivity reactions, intraoperative or postoperative fracture of the femur or tibia, and the need for re-operation, revision, arthrodesis of the involved joint, or amputation of the limb. The safety

objective will compare the complication rates of the Triathlon TS Total Knee System to published rates.

11.4 Protection Against Risks

Subjects 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 wellbeing of the subject, this deviation will be promptly reported to both the EC/IRB and Stryker.

11.5 Potential Benefits to the Subject

There is no guarantee that subjects will personally benefit from inclusion in this study. Subjects 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 device by comparing it to published results for other similar devices. Information gathered in this study may benefit others undergoing this procedure in the future.

12 Ethical Considerations

This study is to be conducted according to United States standards of GCPs and applicable government regulations including 21 CFR Parts 50 and 56 as well as 45 CFR Parts 160 and 164.

This protocol and any amendments will be submitted to a properly constituted independent EC/IRB for formal approval of the study conduct. The decision of the EC/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 Stryker before commencement of this study. The investigator may be asked to provide a list of EC/IRB members and their affiliates to Stryker, if available.

All patients considered for this study will be provided an Informed Patient Consent Form describing this study and providing sufficient information for patients to make an informed decision about their participation. This Informed Patient Consent Form must be modified to contain center specific information and submitted with the protocol for review and approval by the EC/IRB for the study. The formal consent of a patient, using the EC/IRB approved Informed Patient Consent Form, must be obtained before that patient is submitted to any study procedure. This Informed Patient Consent Form must be signed by the patient or legally acceptable surrogate and the investigator-designated research professional obtaining the consent.

13 Study Finances

13.1 Funding Source

This study is financed by Stryker Orthopaedics.

13.2 Conflict of Interest

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

13.3 Subject Stipends or Payments

Subject attrition can occur for a variety of reasons, including a subject's loss of health insurance coverage. In a case where a patient has lost health insurance coverage and no other coverage is available, Stryker may, on a case-by-case basis, reimburse investigators for office visits and radiographic charges for subjects involved in this study in order to facilitate data retrieval. The physician or the office staff should contact the CSM prior to scheduling the subject to discuss this possibility and receive pre-approval. After receipt of the completed data forms, the physician must submit either evidence of coverage denial (e.g. explanation of benefits) or a letter explaining that the subject 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 subjects lose insurance coverage after enrollment into the study
- An insurance carrier refuses to pay for a follow-up visit and/or radiographs
- An insurance carrier refuses to provide a subject referral to see the investigator for follow-up

Additionally at pre-determined study visit intervals, Stryker may reimburse subjects with a modest stipend 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.

14 References

1. Agarwal S, Azam A, Morgan-Jones R. Metal Metaphyseal sleeves in revision total knee replacement. Bone Joint J. 2013; 95-B:1640-1644.
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3. Barrack R, Rorabeck C, Burt M, Sawhney J. Pain at the end of the stem after revision total knee arthoplasty. Clin Orthop and Relat Res. 1999; 367:216-225.
4. Rao BM, Kamal TT, Vafaye J, Moss M. Tantalum cones for major osteolysis in revision knee replacement. Bone Joint J. 2013; 95-B:1069-1074.
5. Radnay CS, Scuderi GR. Management of bone loss: augments, cones, offset stems. Clin Orthop and Relat Res. 2006; 446: 83-92.
6. Engh GA, Ammeen DJ. Bone loss with revision total knee arthroplasty: defect classification and alternatives for reconstruction. Instr Course Lect. 1999; 48: 167-175.
7. Qiu YY, Yan CH, Chiu KY, Ng FY. 2011. Review article: Bone defect classifications in revision total knee arthroplasty. Journal of Orthopaedic Surgery. 2011; 19: 238-243.
8. Meneghini RM, Lewallen DG, Hanssen AD. Use of porous tantalum metaphyseal cones for severe tibial bone loss during revision total knee replacement. J Bone Joint Surg. 2008; 90-A: 78-84.
9. Scuderi GR, Bourne RB, Noble PC, Benjamin JB, Lonner JH, Scott WN. The new Knee Society knee scoring system. Clin Orthop and Relat Res. 2012; 470: 3-19.
10. Ewald FC. The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. Clin Orthop and Relat Res. 1989; 248: 9-12.

Appendix A

FDA 510(k) Clearance Letters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2015

Stryker Orthopaedics
Ms. Margaret Klippel
Associate Strategic Regulatory Affairs Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K143393
Trade/Device Name: Triathlon® Tritanium® Cone Augments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: November 25, 2014
Received: November 26, 2014

Dear Ms. Klippel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Margaret Klippel
Associate Strategic Regulatory Affairs Manager
Howmedica Osteonics Corp
Margaret.klippel@stryker.com
Ph: 201-831-5559
Fax: 201-831-4559

Date Prepared: November 25, 2014

Proprietary Name: Triathlon® Tritanium® Cone Augments

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. (888.3565)
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)

Product Codes: MBH, JWH

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:

- Zimmer Trabecular Metal Knee System Augments (K053340)
- DePuy Universal Gription™ TF Cones (Knee) – DePuy Orthopaedics (K100391)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® Tritanium® Tibial Baseplate (K123486)
- Triathlon® Tritanium® Metal Backed Patella (K132624)

Device Description:

The Triathlon® Tritanium® Cone Augment is an extension of the Triathlon® Total Knee System product line intended to be used as an optional accessory component in primary or revision Total Knee Arthroplasty. It is a sterile, single-use device that is compatible for use with other Triathlon® Total Knee System components. The Triathlon® Tritanium® Cone Augment is composed of commercially pure titanium (raw material per ASTM F1580, processed material per ASTM F67).

The subject device is designed to be used with the Triathlon® TS femoral components and Triathlon® Universal baseplates and is compatible with other Triathlon® Total Knee System

components. The cones are intended to be cemented to the respective Triathlon femoral and/or tibial component, and are intended for fixation within the proximal tibia or distal femur with or without bone cement. Tritanium Femoral and Tibial Cones are intended to be used where there is a femoral and/or tibial metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration.

There are three designs of Triathlon Tritanium Cone Augments:

- Femoral Cone Augments
- Symmetric Tibial Cone Augments
- Asymmetric Tibial Cone Augments

Intended Use:
The Triathlon® Tritanium® Cone Augment is intended for use in primary or revision total knee arthroplasty where there is a femoral and/or tibial metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration. The Triathlon Tritaium Cone Augment is intended to be affixed to the mating femoral and/or tibial component using bone cement. The cones are intended for fixation as an assembled construct in the distal femur and/or proximal tibia, with or without bone cement.

Indications:
The Triathlon Tritanium Cone augments have the same Indications for Use as the Triathlon TS Total Knee System – additional indications for cone augments are noted below.

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:

- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon® Tritanium® Cone Augment components are intended for cemented or cementless use.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Triathlon® Tritanium® Cone Augment is substantially equivalent to its predicate in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial equivalence:

- Cantilever Fatigue Testing in accordance with ASTM F1800- Cone augments survived ten million cycles of clinically relevant loading without failure -

- Torque Testing was performed to establish that the cone augments are able to withstand clinically relevant torque loads

- Plastic Deformation of Cone Augments – cones were metallographically examined in the post-impacted condition – indicated porous surface can withstand impaction without loss of coating integrity

- Micromotion of Triathlon Tibial Cone Augments – comparative testing was performed to evaluate the initial stability of the Triathlon Tibial Cone construct within the prepared

simulated tibial cavity during a simulated stair descent activity. Micromotion of the baseplate/cone construct with respect to the polyurethane foam constructs used to simulate the proximal tibia was recorded for Triathlon cone constructs and compared to the micromotion of the Zimmer Trabecular metal cone constructs (predicate device). This testing indicates that the Triathlon Tibial Cone Augments are at least equivalent to the Zimmer Trabecular Metal Cones in their ability to resist micromotion.

- Triathlon Tritanium Femoral Cone Augment Micromotion - comparative testing was performed to evaluate the initial stability of the Triathlon Femoral Cone construct within the prepared simulated femoral cavity during a normal walking profile. This testing indicates that the Triathlon Femoral Cone Augment is at least equivalent to the Zimmer Femoral Cone Augment in the ability to resist micromotion.

- Characterization of the Physical Properties of the Triathlon Tritanium Cone Augment – this testing established that the porous coating meets the requirements outlined in the FDA guidance documents, "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement", April 28, 1994, and FDA Guidance Document, "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses, Guidance for Industry and FDA", January 16, 2003.

- Characterization of the Material Chemistry of the Triathlon Tritanium Cone Augment - the results of the chemical analysis illustrates that the material meets the requirements set forth in ASTM F67 for Grade 4 unalloyed titanium material, and is similar to a reference device

- Characterization of the Mechanical Properties of Triathlon Tritanium Cone Augments - testing was performed to characterize the mechanical properties of cone augments. Surface treated test coupons processed identically to the final device were used. The subject devices met or exceeded the pre-established performance criteria, and are similar to the reference device in terms of performance criteria.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Triathlon® Tritanium® Cone Augment is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143393

Device Name
Triathlon® Tritanium® Cone Augments

Indications for Use *(Describe)*

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:
- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:
- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:
- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07432

OCT 15 2007

Re: K072221
Trade/Device Name: Triathlon® TS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 27, 2007
Received: September 28, 2007

Dear Ms. Rogers:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

OCT 15 2007

stryker Howmedica OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the Triathlon® TS Knee System

Proprietary Name:	Triathlon® TS Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3560
Regulatory Class:	~~Class II~~
Device Product Code:	87 JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5612 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	August 8, 2007

Device Description

The Triathlon TS Total Knee System features TS and TS Plus tibial inserts available in sizes 1 through 8 and thicknesses from 9mm to 31mm. These tibial inserts used with the Triathlon TS Total Knee System have been modified. The tibial inserts feature an open cam box with a tibial post slot to accommodate a cobalt chrome tibial post intended for additional stability in the knee joint. The Triathlon TS tibial inserts also feature a metal locking wire for assembly into

previously cleared Triathlon tibial baseplates. The Triathlon TS Plus and the Triathlon TS inserts are available in sequentially crosslinked and standard polyethylene.

Intended Use:

The Triathlon TS Total Knee System tibial components are intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. All tibial components presented in this submission are provided sterile for single-use.

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

The Triathlon TS Total Knee System components are intended for cemented use only.

Substantial Equivalence:

The determination of substantial equivalence of the Triathlon TS Total Knee System tibial inserts is based on its similarities in indications for use, intended use, design and sterilization to Howmedica Osteonics' Triathlon TS Total Knee System (K070095, cleared June 01, 2007).

510(k) Number (if known): K072221

Device Name: Triathlon® TS Knee System

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

The Triathlon TS Total Knee System components are intended for cemented use only.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marlene Brechin for MDM

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

510(k) Number K072221 K072221 BDB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2007

Howmedica Osteonics Corp.
c/o Ms. Tiffani D. Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K070095
Trade/Device Name: Triathlon TS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: May 17, 2007
Received: May 18, 2007

Dear Ms. Rogers:

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.

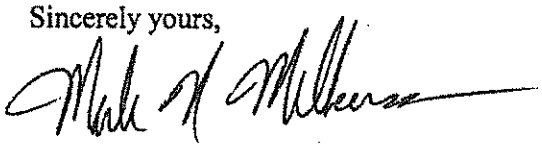
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

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

510(k) Number K070095

510(k) Number (if known): K070095

Device Name: Triathlon® TS Knee System

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

The Triathlon TS Total Knee System components are intended for cemented use only.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K070095
510(k) Summary of Safety and Effectiveness for the
Triathlon® TS Knee System

JUN - 1 2007

Proprietary Name:	Triathlon® TS Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3560
Regulatory Class:	Class II
Device Product Code:	87 JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5412 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	June 1, 2007

Device Description

A total stabilizing version of the Triathlon Total Knee System has been developed and will now include femoral components and tibial inserts compatible with the Triathlon universal tibial components cleared previously. The new Triathlon TS Knee is designed to accommodate patients with severely deficient bone stock who require additional components for increased stabilization. The Triathlon TS System will include femoral components, stem extenders, offset adapters, stems, and tibial inserts in standard and TS Plus design. Implants will be available in sizes 1 through 8. Product descriptions, product codes and engineering drawings are provided for review.

Intended Use:

The Triathlon TS Total Knee System components are intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. All total knee components presented in this submission are provided sterile for single-use.

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

The Triathlon TS Total Knee System components are intended for cemented use only.

Substantial Equivalence:

The determination of the substantial equivalence of the Triathlon TS total knee system is based on similarities in intended use, design and sterilization to the Howmedica Total Stabilizing Total Knee System (K973164, cleared August 22, 1997), Triathlon PS Knee System (K031729, cleared September 2, 2003 and K042993 cleared January 12, 2005) and the Triathlon® Total Knee System (K053514, cleared January 26, 2006).

Appendix B

Component Listing

Triathlon Tritanium Cone Augments and Triathlon TS Total Knee System Protocol-Specified Component List:

Catalog Number	
Triathlon Tritanium Femoral Cone Augment	
5549-A-321	5549-A-322
5549-A-331	5549-A-332
5549-A-341	5549-A-342
5549-A-351	5549-A-352
5549-A-361	5549-A-362
5549-A-371	5549-A-372
Triathlon Tritanium Central Femoral Cone Augment	
5549-A-621	5549-A-622
5549-A-641	5549-A-642
5549-A-651	5549-A-652
5549-A-661	5549-A-662
5549-A-671	5549-A-672
Triathlon Tritanium Symmetric Tibial Cone Augment	
5549-A-110	
5549-A-120	
5549-A-130	
5549-A-140	
5549-A-150	
Triathlon Tritanium Asymmetric Tibial Cone Augment	
5549-A-221	5549-A-222
5549-A-231	5549-A-232
5549-A-241	5549-A-242
5549-A-251	5549-A-252
Triathlon TS Femoral Component	
5512-F-101	5512-F-102
5512-F-201	5512-F-202
5512-F-301	5512-F-302
5512-F-401	5512-F-402
5512-F-501	5512-F-502
5512-F-601	5512-F-602
5512-F-701	5512-F-702
5512-F-801	5512-F-802
Triathlon TS Tibial Baseplate	
5521-B-100	
5521-B-200	
5521-B-300	
5521-B-400	
5521-B-500	
5521-B-600	
5521-B-700	
5521-B-800	

Catalog Number			
	Triathlon TS Plus Tibial Insert		
5537-G-109	5537-G-109-E	5537-G-509	5537-G-509-E
5537-G-111	5537-G-111-E	5537-G-511	5537-G-511-E
5537-G-113	5537-G-113-E	5537-G-513	5537-G-513-E
5537-G-116	5537-G-116-E	5537-G-516	5537-G-516-E
5537-G-119	5537-G-119-E	5537-G-519	5537-G-519-E
5537-G-122	5537-G-122-E	5537-G-522	5537-G-522-E
5537-G-125	5537-G-125-E	5537-G-525	5537-G-525-E
5537-G-128	5537-G-128-E	5537-G-528	5537-G-528-E
5537-G-131	5537-G-131-E	5537-G-531	5537-G-531-E
5537-G-209	5537-G-209-E	5537-G-609	5537-G-609-E
5537-G-211	5537-G-211-E	5537-G-611	5537-G-611-E
5537-G-213	5537-G-213-E	5537-G-613	5537-G-613-E
5537-G-216	5537-G-216-E	5537-G-616	5537-G-616-E
5537-G-219	5537-G-219-E	5537-G-619	5537-G-619-E
5537-G-222	5537-G-222-E	5537-G-622	5537-G-622-E
5537-G-225	5537-G-225-E	5537-G-625	5537-G-625-E
5537-G-228	5537-G-228-E	5537-G-628	5537-G-628-E
5537-G-231	5537-G-231-E	5537-G-631	5537-G-631-E
5537-G-309	5537-G-309-E	5537-G-709	5537-G-709-E
5537-G-311	5537-G-311-E	5537-G-711	5537-G-711-E
5537-G-313	5537-G-313-E	5537-G-713	5537-G-713-E
5537-G-316	5537-G-316-E	5537-G-716	5537-G-716-E
5537-G-319	5537-G-319-E	5537-G-719	5537-G-719-E
5537-G-322	5537-G-322-E	5537-G-722	5537-G-722-E
5537-G-325	5537-G-325-E	5537-G-725	5537-G-725-E
5537-G-328	5537-G-328-E	5537-G-728	5537-G-728-E
5537-G-331	5537-G-331-E	5537-G-731	5537-G-731-E
5537-G-409	5537-G-409-E	5537-G-809	5537-G-809-E
5537-G-411	5537-G-411-E	5537-G-811	5537-G-811-E
5537-G-413	5537-G-413-E	5537-G-813	5537-G-813-E
5537-G-416	5537-G-416-E	5537-G-816	5537-G-816-E
5537-G-419	5537-G-419-E	5537-G-819	5537-G-819-E
5537-G-422	5537-G-422-E	5537-G-822	5537-G-822-E
5537-G-425	5537-G-425-E	5537-G-825	5537-G-825-E
5537-G-428	5537-G-428-E	5537-G-828	5537-G-828-E
5537-G-431	5537-G-431-E	5537-G-831	5537-G-831-E

Catalog Number			
	Triathlon PS Tibial Insert		
5532-G-109	5532-G-109-E	5532-P-109	5532-P-109-E
5532-G-209	5532-G-209-E	5532-P-209	5532-P-209-E
5532-G-309	5532-G-309-E	5532-P-309	5532-P-309-E
5532-G-409	5532-G-409-E	5532-P-409	5532-P-409-E
5532-G-509	5532-G-509-E	5532-P-509	5532-P-509-E
5532-G-609	5532-G-609-E	5532-P-609	5532-P-609-E
5532-G-709	5532-G-709-E	5532-P-709	5532-P-709-E
5532-G-809	5532-G-809-E	5532-P-809	5532-P-809-E
5532-G-111	5532-G-111-E	5532-P-111	5532-P-111-E
5532-G-211	5532-G-211-E	5532-P-211	5532-P-211-E
5532-G-311	5532-G-311-E	5532-P-311	5532-P-311-E
5532-G-411	5532-G-411-E	5532-P-411	5532-P-411-E
5532-G-511	5532-G-511-E	5532-P-511	5532-P-511-E
5532-G-611	5532-G-611-E	5532-P-611	5532-P-611-E
5532-G-711	5532-G-711-E	5532-P-711	5532-P-711-E
5532-G-811	5532-G-811-E	5532-P-811	5532-P-811-E
5532-G-113	5532-G-113-E	5532-P-113	5532-P-113-E
5532-G-213	5532-G-213-E	5532-P-213	5532-P-213-E
5532-G-313	5532-G-313-E	5532-P-313	5532-P-313-E
5532-G-413	5532-G-413-E	5532-P-413	5532-P-413-E
5532-G-513	5532-G-513-E	5532-P-513	5532-P-513-E
5532-G-613	5532-G-613-E	5532-P-613	5532-P-613-E
5532-G-713	5532-G-713-E	5532-P-713	5532-P-713-E
5532-G-813	5532-G-813-E	5532-P-813	5532-P-813-E
5532-G-116	5532-G-116-E	5532-P-116	5532-P-116-E
5532-G-216	5532-G-216-E	5532-P-216	5532-P-216-E
5532-G-316	5532-G-316-E	5532-P-316	5532-P-316-E
5532-G-416	5532-G-416-E	5532-P-416	5532-P-416-E
5532-G-516	5532-G-516-E	5532-P-516	5532-P-516-E
5532-G-716	5532-G-716-E	5532-P-716	5532-P-716-E
5532-G-816	5532-G-816-E	5532-P-816	5532-P-816-E
5532-G-119	5532-G-119-E	5532-P-119	5532-P-119-E
5532-G-219	5532-G-219-E	5532-P-219	5532-P-219-E
5532-G-319	5532-G-319-E	5532-P-319	5532-P-319-E
5532-G-419	5532-G-419-E	5532-P-419	5532-P-419-E
5532-G-519	5532-G-519-E	5532-P-519	5532-P-519-E
5532-G-619	5532-G-619-E	5532-P-619	5532-P-619-E
5532-G-719	5532-G-719-E	5532-P-719	5532-P-719-E
5532-G-819	5532-G-819-E	5532-P-819	5532-P-819-E
5532-G-122	5532-G-122-E	5532-P-122	5532-P-122-E
5532-G-222	5532-G-222-E	5532-P-222	5532-P-222-E
5532-G-322	5532-G-322-E	5532-P-322	5532-P-322-E
5532-G-422	5532-G-422-E	5532-P-422	5532-P-422-E
5532-G-522	5532-G-522-E	5532-P-522	5532-P-522-E
5532-G-622	5532-G-622-E	5532-P-622	5532-P-622-E
5532-G-722	5532-G-722-E	5532-P-722	5532-P-722-E
5532-G-822	5532-G-822-E	5532-P-822	5532-P-822-E
5532-G-125	5532-G-125-E	5532-P-125	5532-P-125-E
5532-G-225	5532-G-225-E	5532-P-225	5532-P-225-E
5532-G-325	5532-G-325-E	5532-P-325	5532-P-325-E
5532-G-425	5532-G-425-E	5532-P-425	5532-P-425-E
5532-G-525	5532-G-525-E	5532-P-525	5532-P-525-E
5532-G-625	5532-G-625-E	5532-P-625	5532-P-625-E
5532-G-725	5532-G-725-E	5532-P-725	5532-P-725-E
5532-G-825	5532-G-825-E	5532-P-825	5532-P-825-E

Catalog Number			
	Triathlon Patellar Component		
5550-G-278	5550-G-278-E	5550-L-278	5550-L-278-E
5550-G-298	5550-G-298-E	5550-L-298	5550-L-298-E
5550-G-319	5550-G-319-E	5550-L-319	5550-L-319-E
5550-G-339	5550-G-339-E	5550-L-339	5550-L-339-E
5550-G-360	5550-G-360-E	5550-L-360	5550-L-360-E
5550-G-391	5550-G-391-E	5550-L-391	5550-L-391-E
5551-G-299	5551-G-299-E	5551-L-299	5551-L-299-E
5551-G-320	5551-G-320-E	5551-L-320	5551-L-320-E
5551-G-350	5551-G-350-E	5551-L-350	5551-L-350-E
5551-G-381	5551-G-381-E	5551-L-381	5551-L-381-E
5551-G-401	5551-G-401-E	5551-L-401	5551-L-401-E
	Triathlon TS Stems - Cemented		
5560-S-109	5560-S-112		5560-S-115
5560-S-209	5560-S-212		5560-S-215
5560-S-309	5560-S-312		5560-S-315
	Triathlon TS Stems- Cementless		
5565-S-010		5566-S-010	
5565-S-011		5566-S-011	
5565-S-012		5566-S-012	
5565-S-013		5566-S-013	
5565-S-014		5566-S-014	
5565-S-015		5566-S-015	
5565-S-016		5566-S-016	
5565-S-017		5566-S-017	
5565-S-018		5566-S-018	
5565-S-019		5566-S-019	
5565-S-020		5566-S-020	
5565-S-021		5566-S-021	
5565-S-022		5566-S-022	
5565-S-023		5566-S-023	
5565-S-024		5566-S-024	
5565-S-025		5566-S-025	
Triathlon Stem Extender			
5571-S-025			
5571-S-050			
Triathlon TS Offset Adapter			
5570-S-020			
5570-S-040			
5570-S-060			
5570-S-080			

Catalog Number		
Triathlon TS Femoral Distal Augments		
5540-A-101	5541-A-101	5542-A-101
5540-A-201	5541-A-201	5542-A-201
5540-A-301	5541-A-301	5542-A-301
5540-A-401	5541-A-401	5542-A-401
5540-A-501	5541-A-501	5542-A-501
5540-A-601	5541-A-601	5542-A-601
5540-A-701	5541-A-701	5542-A-701
5540-A-801	5541-A-801	5542-A-801
5540-A-102	5541-A-102	5542-A-102
5540-A-202	5541-A-202	5542-A-202
5540-A-302	5541-A-302	5542-A-302
5540-A-402	5541-A-402	5542-A-402
5540-A-502	5541-A-502	5542-A-502
5540-A-602	5541-A-602	5542-A-602
5540-A-702	5541-A-702	5542-A-702
5540-A-802	5541-A-802	5542-A-802
Triathlon TS Femoral Posterior Augments		
5543-A-100	5544-A-100	
5543-A-200	5544-A-200	
5543-A-300	5544-A-300	
5543-A-400	5544-A-400	
5543-A-500	5544-A-500	
5543-A-600	5544-A-600	
5543-A-700	5544-A-700	
5543-A-800	5544-A-800	
Triathlon Femoral Augment Locking Screws		
5540-A-000		
5545-A-000		
Triathlon TS Tibial Augments		
5545-A-101	5546-A-101	
5545-A-201	5546-A-201	
5545-A-301	5546-A-301	
5545-A-401	5546-A-401	
5545-A-501	5546-A-501	
5545-A-601	5546-A-601	
5545-A-701	5546-A-701	
5545-A-801	5546-A-801	
5545-A-102	5546-A-102	
5545-A-202	5546-A-202	
5545-A-302	5546-A-302	
5545-A-402	5546-A-402	
5545-A-502	5546-A-502	
5545-A-602	5546-A-602	
5545-A-702	5546-A-702	
5545-A-802	5546-A-802	

Appendix C

Study Advertisements

Clinical Trial with the Triathlon Tritanium Cone Augments

Dr. (name) of (practice) is participating in a clinical study evaluating a revision knee replacement with a new ancillary device in patients who are eligible for a revision total knee replacement.

The **Triathlon Tritanium Cone Augments** are intended for cemented use respective to the femoral and tibial components, and cementless use with respect to the prepared bone. They are compatible with other Stryker components as well. These augments are currently being sold in the United States and are implanted in patients who need revision knee surgery.

Dr. (name) is one of 5 to 8 surgeons nationwide selected to enroll qualifying patients into this clinical study. The data collected will be used to evaluate short-term (5-year) performance of the components following surgery.

The study includes males and non-pregnant females between 18 and 75 years of age. These patients must be candidates for a revision knee replacement. These patients must also be able to comply with requirements following surgery including weight bearing restrictions and self-evaluation questionnaires. Enrolled patients will be required to come in for an evaluation and x-rays before surgery and follow-up evaluations and x-rays at 6 weeks, 6 months, 1 year, 2 years, and 5 years after surgery.

Meeting all of the above criteria does not guarantee participation in the study. Further consultation and a screening evaluation with the physician are necessary to ensure this is the right study for you. Study personnel at the site will explain all the details of the study to you so you can make an informed decision as to whether or not you would like to participate.

If you are interested in participating in this study, please contact Dr. (name) or (study coordinator name) at the numbers listed below for further details.

Your request for information about this study in no way commits you to participate. In order to participate, you will have to meet specific criteria and sign a consent form that details all aspects of the study, the device and the risks associated with revision knee surgery.

Dr. (name)
Practice Name
Telephone Number

Study Coordinator Name
Title
Telephone Number

Appendix D

Model Informed Patient Consent

Informed Patient Consent

I. Study Title: A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments.

II. Description of the Study

You have been asked to be in this research study because your doctor thinks you need surgery to replace your knee joint. About 145 people from up to 12 different hospitals will be in this study.

The reason this study is being done is to see how successful a knee replacement using parts called the Triathlon TS Total Knee System and Triathlon Tritanium Cone Augments will be. Some of these parts will be put in using bone cement. The study will be able to tell how the knee replacement parts are performing by looking at whether there is a need to remove or replace the femoral component or baseplate due to the parts getting loose near the bone, and not because of an infection. This will be compared with how much this happens to patients who have a knee replacement with a similar cone augment.

This study is being done by Stryker Orthopaedics (the maker of the knee replacement, also called the Sponsor) and your doctor. We are doing this study to review the performance of the Stryker Orthopaedics Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments knee replacement.

Your doctor and his staff will ask you some questions during this visit. Based on the requirements of the study, you may or may not be chosen to be in the study.

Fitting all of these requirements does not mean you will be in the study. The doctor also has to examine you to make sure the study is right for you. The staff at the doctor's office will tell you everything about the study. Then you can decide if you want to be in the study or not.

Your participation in the study will last for 10 years following your study surgery. Your doctor will examine you before surgery and during surgery. You will have surgery and your doctor will tell us the details of your surgery. During the visit before surgery you will need to fill out forms about your health. Your doctor will also collect other information and x-rays that would be collected at a normal visit.

He will then examine you for the study after your surgery. During your visits to the doctor after surgery, your doctor will figure out how your knee is performing and take x-rays. These x-rays are the same kind you would have if you were not in the study.

At your visits to the doctor after surgery, your doctor will ask you to fill out questionnaire forms. These forms will be about your health. These visits will follow the evaluation schedule below:

Surgeon Evaluations	Before Surgery	6 Weeks	6 Months	1 Year	2 Years	5 Years	Annually 6 Years - 10 Years
Demographics and Current Medical Conditions	X						
2011 Knee Society Score	X	X	X	X	X	X	
AP X-ray*	X	X	X	X	X	X	
ML X-ray	X	X	X	X	X	X	
Merchant view X-ray	X	X	X	X	X	X	
Patient Questionnaires							
SF-12	X	X	X	X	X	X	
LEAS	X	X	X	X	X	X	
HSS Patella Score	X	X	X	X	X	X	
EQ-5D	X	X	X	X	X	X	
Stem Tip Pain Diagram	X	X			X	X	
Follow-Up Questionnaire							X

*Bilateral Anteroposterior (AP) X-ray: A Long-standing AP x-ray will be taken before surgery and at 6 weeks after surgery. At 6 months, 1 year, 2 years and 5 years after surgery, a standard AP x-ray will be taken.
(Bilateral AP x-rays are preferred. However, unilateral AP x-rays may be submitted at these timepoints, if bilateral images are not available)

Mediolateral (ML) X-ray: A standard ML x-ray will be taken before surgery and at 6 weeks, 6 months, 1 year, 2 years and 5 years after surgery.

Merchant view X-ray: A standard Merchant view x-ray will be taken before surgery and at 6 weeks, 6 months, 1 year, 2 years and 5 years after surgery.

Short Form-12 (SF-12): The SF-12 is a 12-item patient questionnaire that evaluates general health and well-being.

Lower Extremity Activity Scale (LEAS): The LEAS is a patient questionnaire designed to reflect patient activity.

Hospital for Special Surgery Patella Score: The HSS Patella Score incorporates both patient reported symptoms and surgeon reported data specific to the front of the knee.

EuroQol-5D (EQ-5D): The EQ-5D is a standardized instrument that evaluates the patient's current health state.

Stem Tip Pain Diagram: The Stem Tip Pain Diagram is an anatomic diagram the patient completes to demonstrate the level and location of pain in their thigh or shin. This questionnaire is only applicable preoperative if the patient has a long stem previously implanted.

Follow-Up Questionnaire: The Follow-up Questionnaire is a short patient questionnaire intended to provide information on patient satisfaction, pain, whether the study device is in place and reportable complications.

III. Condition and Care after Surgery

Your doctor will tell you what to do to get better after your surgery. Like with any surgery, your body takes time to heal. That amount of time will be related to the surgery and your health. While you are healing, you may experience pain because of the surgery. This pain might last a few months after the surgery.

Your doctor will tell you to use crutches, a walker, or a cane after your surgery. This will take some weight off of your knee. This can help your knee replacement last longer. You must follow your doctor's orders on using a cane, crutches, or walker.

The goal of this surgery is to lessen pain and improve your knee performance. You will need to see your doctor at the scheduled follow-up visits after your surgery for an evaluation of your knee replacement.

IV. Possible Risks

This study looks at how your knee replacement is performing. The Food and Drug Administration (FDA) already allows this knee replacement to be sold in the United States. There are no extra risks for you because you are in this study, just the normal risks of knee replacement surgery. You may need to spend a little more time in the doctor's office to fill out paperwork. If the doctors and scientists find out any new information during this study that might make you change your mind about being in the study, you will get that new information.

There are some risks in knee surgery. These might be: moderate to severe pain; breaking the knee replacement parts or the surrounding bones; movement of parts of the replacement inside your body; parts of the replacement sinking; parts of the replacement moving out of their normal position; allergies to the metal parts of the replacement; removal of one or more of the parts; loosening and infection; rubbing of parts of the replacement which might lead to losing part of the bone; disorders of the nerves involving your legs; damage to the nerves; abnormal building up of bone; changes in movement of your blood related to your heart, blood and lymph vessels; problems with urinating; problems with your stomach or intestines; problems with blood vessels like blood clots; lung problems like pneumonia; a clogged blood vessel; or a heart attack.

V. Potential Benefits

You might not benefit personally from being in the study, but the results might help out others that have knee replacement surgery in the future.

VI. Other Types of Treatment

You have talked about other possible treatments with your doctor. These treatments might be conservative treatment that is not surgery or no treatment at all.

You can say no to being a part of this study. This will not change any part of your knee surgery. Your doctor can tell you detailed facts about this treatment and the benefits of other types of treatment you can have. You should feel free to talk with your doctor about other options.

VII. Making Financial Information Known

Your doctor and/or the hospital can be paid money from the company that made the knee replacement. This money would be to pay for the cost of doing the study or for other reasons. If you want to know more about this, you can ask your doctor or his staff.

VIII. Privacy

If you say yes to being a part of this study, your medical records and identity will be kept private. They will be kept private based on the law. The records will not be given to anyone unless you give written permission.

If you sign this consent form, you allow Stryker Orthopaedics employees to see your medical records. You also allow people to see your records who look at how safe and effective medical products are. These people also make sure that medical treatment and research studies are safe. Your name and identity will not be in those records.

IX. Cost to Be in the Study

Your procedure is a routine revision knee surgery should be covered by your insurance carrier.

Additionally, you will be offered a stipend in the form of a debit card for various follow-up visits held in your doctor's office. You must complete all of the applicable questionnaires and evaluations in order to receive the stipend per visit. You can learn more about the program from your study doctor and his staff.

X. Device Retrieval Analysis Study

If [Investigators' Names] finds it medically necessary to perform a knee revision because of device failure, Stryker Orthopaedics has a procedure to test the parts.

I understand that Stryker Orthopaedics Corporation makes the implant and runs the study. I understand that Stryker Orthopaedics will ask my doctor to send any removed knee replacement parts to them. My doctor will send them to the Product Surveillance department at Stryker Orthopaedics. They will test these parts, and this can be a part of being in the study.

I allow my doctor and to give Stryker Orthopaedics (the Sponsor) any knee implant parts that have been removed. I also allow my doctor to give Stryker Orthopaedics other information. This other information is my name, birth date, and details about my knee surgery. Then they can test the knee replacement parts that have been taken out. They can give the company and the doctor the results of those tests.

My doctor will get the results of this testing. I understand that I will not get these parts back. I also understand that I will not get the results of any tests that are done on those parts.

I understand that nobody outside of the Sponsor will see my removed knee replacement parts.

I understand that I will let my doctors and the Sponsor see information about my identity. I also understand that nobody else will see that information. I understand that if I want to see this information, I can ask my doctor for it.

I understand that I can I decide I do not want to let these knee replacement parts to be used anymore. I can also decide if I do not want my identity information to be used anymore. I understand that I will need to say this in writing. I understand that any information from before that is still allowed to be used.

Records about me will be kept private. I can choose whether I want to allow my knee replacement parts to be studied if they are taken out. I understand I am allowed to say no to having my knee replacement parts studied. I also understand that I can stop being in the study whenever I want. If I choose to stop being in the study, my doctor will not change my care or treatment.

I have signed below and have read and understood what is written above. I allow for information about my identity to be released. My signature shows that I have had a chance to ask questions about this removed knee replacement parts study. My doctor has answered these questions. I have been given a copy of the consent form.

Please check one of the boxes below:

☐ I agree to allow the Sponsor to study any knee replacement parts removed from me.

☐ I do not want to allow the Sponsor to study any knee replacement parts removed from me.

_____ _____

Signature of Subject/Legal Representative Date

XI. Clinical Trial Website Posting

A description of this clinical trial will be on the website http://www.Clinical Trials.gov. The U.S. law says it has to be posted on that website. This Web site will not have any information that can tell other people who you are. The Web site will show some of the results, or maybe even less than that. You can search this Web site whenever you want.

XII. Payment and Medical Treatment Related to Injury

The Sponsor will not give you any money if you have a medical problem related to surgery. Stryker Orthopaedics will not give you free medical treatment. If you have a medical problem related to your surgery, you should call [Investigators' Names] as soon as you can at [Phone Number].

[Institution Name] will not give any money back or free treatment to you either. [Investigators' Names] should tell you about what the hospital does if you have a complication. By signing this consent form, you are not getting rid of any of your rights. Your doctor is still responsible if he does something wrong.

XIII. Access to Data and Privacy

By being part of this study, you are letting your doctor and his staff give the Sponsor information about your health. You also allow people to see your records who look at how safe and effective medical products are. These people also make sure that medical treatment and research studies are safe. This is required by the law. This health information includes all information from the study. It may also include other health information in your medical records. Some of this health information might be from before you joined the study.

The Sponsor will only collect information that they need for the study. They will make sure that the information they get does not have your name or address on it. They will make sure that no one else will see information about your identity.

The Sponsor will use information about your health to do the study. They will use the results of the study to evaluate the performance of the knee replacement parts. They will also use the results to improve the parts that they make. They might also use the information to design new parts.

This permission to use your information does not have an ending date. You can take back this permission to release your health information at any time. You can do this by

telling your doctor in writing. If you say you do not want to be in the study anymore it will not change the work that has already been done in the study. You have to sign this consent form to be in the study. This form also lets your health information be seen by those groups mentioned before. If you take back this consent you cannot be in the study anymore. At the end of the study information about your identity cannot be used anymore.

XIIV. People to Contact

If you have any questions you can call [IRB Name] IRB at [IRB Phone Number]. You can also ask them if you want to know your rights as part of the study. You should contact Dr. [Investigators' Names] as soon as you can at [Phone Number] if you have an injury that is related to the study.

XV. Being in the Study

Being part of this study is your choice. If you do not choose to be in the study, you will not lose any benefits that you are supposed to have. You can decide you do not want to be in the study anymore and will not lose the benefits you are supposed to have.

By signing and dating this form below, you are saying you have read and looked over all sections of this Informed Consent Form. You are also saying someone has answered all of your questions. You are also saying voluntarily consent to be in this research study. If you do not sign this form, you will not be allowed to be in the research study.

_____
Printed name of Subject/Legal Representative

_____ _____
Signature of Subject/Legal Representative Date Signed

_____ _____
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.

Appendix E

Suggested Radiographic Technique

Suggested Radiographic Technique[i]

The following views are required preoperatively and at each postoperative interval specified according to the evaluation schedule to enable evaluation of the bone-prosthesis interfaces.

- Long Standing AP
- AP
- ML
- Merchant (30° of flexion)

General Requirements

A. Appropriate corrections in radiological exposure setting are needed for obese subjects.

B. At least a 14”x17” sized film should be used.

C. If the subject is **bilateral** and a view showing both knees is submitted, **two copies of that view are required**.

D. Both digital and film radiographs are acceptable. **Digital films must be in uncompressed DICOM format.**

E. **A view capturing the complete prosthesis must be submitted to Stryker. Radiographs incompletely displaying components will be rejected.**

F. Each image must have:
   a. Subject’s identification number
   b. Subject’s initials
   c. Date of radiograph
   d. Indication of operative side in the study
   e. Markers for right and left sides, as applicable
   f. Visit interval

AP

A. Long Standing technique[ii]

   a. The subject should be standing with the study knee in 10° flexion. Both knees should be in the view.

   b. The x-ray beam should be directed vertically to the study knee with 5° to 7° angulation toward the subject’s head.

   c. The entire lower extremity, including the ipsilateral and contralateral hip must be visible on the film as shown in Figure 1. The femoral component, the medial

and lateral femoral epicondyles, tibial component and an unobstructed view of the polyethylene tibial insert must be visible on film as well**.**

B. Standard technique

d. The subject should be supine with the knee in full extension and the leg positioned neutrally. Both knees should be in the view.

e. The x-ray beam should be directed vertically to the study knee with 5° to 7° angulation toward the subject's head.

f. The femoral component, the medial and lateral femoral epicondyles, tibial component and an unobstructed view of the polyethylene tibial insert must be visible on film as shown below (Figure 2).

Refer to Figure 1 and 2 for an acceptable AP radiographs.

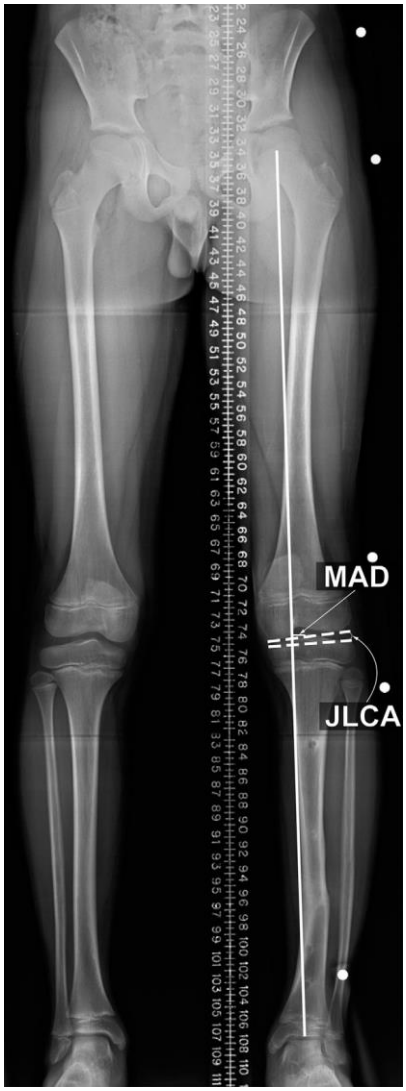


Figure 1. Long Standing AP View - Acceptable

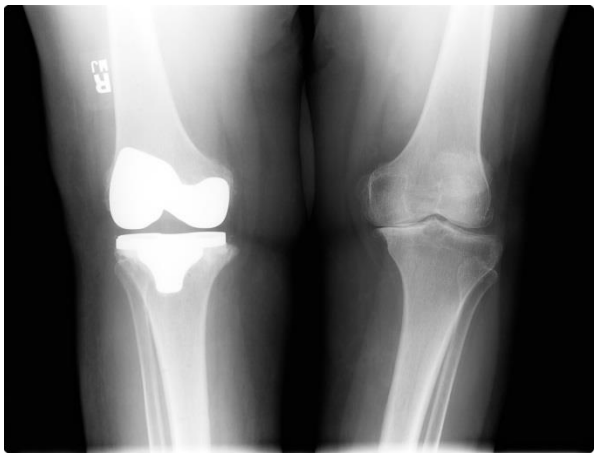


Figure 2. Standard AP View - Acceptable

ML

A. Standard technique

a. The subject should be lying flat on the same side as the study knee. The knee should be flexed 25° to 30°.

b. The x-ray beam should be directed vertically toward the medial aspect of the knee joint perpendicular to the plane of the extremity.

c. The patella, the patellar component, overlapping posterior condyles of the femoral component and tibial component, all in profile, must be visible in this radiograph.

Refer to Figure 2 for an acceptable ML radiograph.

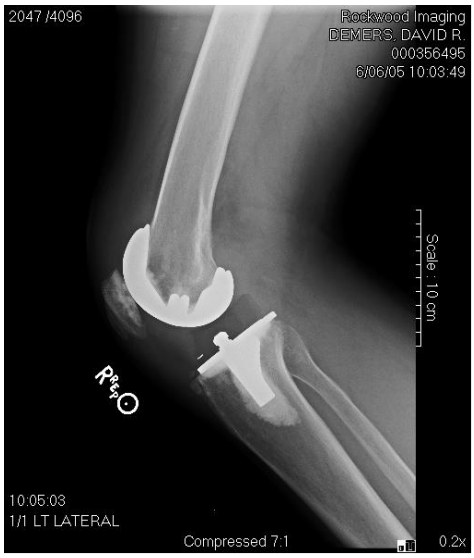


Figure 2. ML View - Acceptable

Merchant (30° of flexion)

A. Standard technique

   a. The subject should be supine with his/her knee flexed about 30° at the table's edge.

   b. A device should be use to maintain flexion at this angle, to which the film cassette should be attached.

   c. The x-ray beam should be directed through the patella at 60° from the vertical axis.

   d. The articular surface of the patella and femur must be visible.

Refer to Figure 3 for an acceptable Merchant (30° of flexion) radiograph.

Figure 3. Merchant (30° of Flexion) View – Acceptable

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[i] Greenspan, A. (1992). *Orthopedic radiology: A practical approach* (2nd ed.). New York: Gower Medical Publishing.

[ii] Sabharwal S. Assessment of Lower Limb Alignment: Supine Fluoroscopy compared with a standing full-length radiograph. J Bone Joint Surg AM.2008; 90: 43-51.

Appendix F

Retrieved Implant Analysis Protocol

RETRIEVED IMPLANT ANALYSIS PROTOCOL

Triathlon Tritanium Cone Augments Outcomes Study

PURPOSE:

To evaluate retrieved Stryker Orthopaedics Triathlon TS Tibial Baseplates, Triathlon TS Femoral Components, Triathlon TS Tibial Inserts, Triathlon Tritanium Cone Augments, and other ancillary components in order to help characterize patterns of wear and potential device-related complications.

METHODS:

A. Subject Selection:

Surgeons participating in the Stryker Orthopaedics Triathlon Tritanium Cone Augments Outcomes Study [510(k) clearance #K070095 – June 1, 2007, 510(k) clearance #K072221 – October 15, 2007, and 510(k) clearance #K143393 – January 13, 2015] will be asked to comply with the Retrieved Implant Analysis Protocol. Whenever possible, subjects who undergo revision/removal of the Stryker Orthopaedics Triathlon TS Total Knee System and/or other ancillary components will be included in this analysis. Subjects will be asked to consent to having their implants analyzed. A sample Informed Patient Consent Form, including a section for implant analysis, is attached to this protocol as Appendix D.

This study protocol will comply with the 2002 HIPAA privacy rule. As such, Stryker will only collect that information which is necessary to support the objectives of the study protocol. Stryker will take precautions to ensure that data received is as de-identified as possible. In the case that some identified information is received, Stryker will ensure that any identifying information is not reported. Study subjects will authorize Stryker to use their retrieved implant(s) and health information in support of the study protocol by completing and signing the Informed Patient Consent Form. A subject also has the option to sign the Informed Patient Consent Form for study participation but decline participation in the Retrieved Implant Analysis Protocol by checking off the appropriate selection in that section of the consent. Should a subject choose to withdraw authorization, Stryker may use data collected prior to the withdrawal of authorization in order to maintain data integrity.

B. Specimen Handling:

The Stryker Orthopaedics Triathlon TS Tibial Baseplates, Triathlon TS Femoral Components, Triathlon TS Tibial Inserts, Triathlon Tritanium Cone Augments, and/or ancillary component(s) obtained at the time of revision/removal should be placed in neutral buffered formalin. Each specimen container should be carefully labeled with subject initials, operative side, surgeon name and the component(s) included for analysis. Whenever possible, relevant radiographic studies and a clinical summary should be placed on the outside of the shipping container along with the specimen.

All specimens should be placed into a sufficient quantity of 10% formalin for a minimum of 24 hours prior to shipping.

After the specimens have been immersed in 10% formalin for a minimum of 24 hours, they should be transferred to a leak proof container with a quantity of 10% formalin sufficient to keep the specimens moist.

C. Recommendations for Packing and Shipping Explants To Stryker Orthopaedics

Please contact the Triathlon Tritanium Cone Augments Outcomes Study CSM, identified on the Stryker Orthopaedics Contact Sheet, via phone or email once the scheduled revision/removal surgery has been performed in order to notify the study team of the intended revision/removal.

A confirmation with the Product Inquiry (PI) number, including shipping instructions, will be provided by Stryker once the event is reported to Stryker. Please ensure that the provided PI number is marked on the outside of the shipping container.

RESULTS

A report suitable for routine patient care will be provided to each surgeon by request.

Appendix G

Draft Specifications for Electronic Case Report Forms

Annotated Study Book for Study Design: TriathCone

Study Design Version: 1.4

Sponsor: Stryker

Protocol: TriathCone

A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon TS Total Knee System with Triathlon Tritanium Cone Augments

Generated by Central Designer TM

May 8, 2015 5:20PM

Time and Events Schedule For Study Design: TriathCone

	Element		System										
	Assessment	**CRF**	**System Screening (SCR) [S]**	**System Enrollment (ENR) [S]**	**Baseline / Pre-Op (BASE/PREOP) [S]**	**Surgical Details (INTRAOP) [S]**	**6WK (6WK) [S/D]**	**6MO (6MO) [S/D]**	**1YR (1YR) [S/D]**	**2YR (2YR) [S/D]**	**5YR (5YR) [S/D]**	**Adverse Event (AE) [S]**	**Study Completion (STUDYCOMP) [S]**
	Visit Start Hours		0	0	0	1	1009	5041	9409	18169	18170	18171	18172
1	System Screening	SCR	1										
2	System Enrollment	ENR		1									
3	Date of Visit	DOV			1	1	1	1	1	1	1		
4	Inclusion / Exclusion	IE			2								
5	Demographics	DM			3								
6	CENSOR	CENSOR			4								
7	Knee Society Score: Pre-Op	PREKSS2011			5								
8	SF-12v2 Health Survey	SF12			6		4	4	4	4	4		
9	Lower Extremity Activity Scale	LEAS			7		5	5	5	5	5		
10	HSS Patella Score	HSSPAT			8		6	6	6	6	6		
11	EQ-5D Health Questionnaire	EQ5D			9		7	7	7	7	7		
12	End of Stem Pain	ESP			10		8			8	8		
13	Previous Implant Information	PIF				2							
14	Surgical Details	SURG				3							
15	Surgical Prostheses	SP				4							
16	Knee Society Score: Post-Op	POSTKSS2011					2	2	2	2	2		
17	Post-Op Events	POEVENT					3-DF	3-DF	3-DF	3-DF	3-DF		
18	Adverse Event TriathCone	AE										1-RF	
19	Study Termination	TERM											1

Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

TriathCone: System Screening (SCR) [SCR]		
1. * ✔	Subject Initials [Subj Initials]	**[SCRINIT]** Enter "-", if subject does not have a middle initial. A3

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

TriathCone: System Enrollment (ENR) [ENR]		
1.	Subject Number *[read-only]* [Subj Number]	**[SUBID]** A10
2. * ✔	Scheduled Surgery Date [Scheduled Surgery Date]	**[SCHDSURG]** Req / Req / Req (2015-2025)

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

TriathCone: DOV (DOV) [DOV]		
1.*	Date of Visit [Date of Visit]	**[DOVDT]** Req / Req / Req (2015-2025)

Key: [*] = Item is required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

TriathCone: Inclusion / Exclusion (IE) [IE]

General Information [IE_S1]

1.* ✔	Operative Side [Operative Side]	**[OPSIDE]** Right Left
2.* ✔	Informed Consent Date Signed [Informed Consent Date Signed]	**[CONSENT]** Req / Req / Req (2015-2025)

Inclusion Criteria [IE_S2]

**All of the below must be answered "Yes" for the patient to be included in the study.

3.* ✔	Patient has signed an IRB/EC approved study specific Informed Patient Consent Form. [INCLUSION 1]	**[IEINC1]** Yes No
4.* ✔	Patient is a male or non-pregnant female age 18 or older at time of study device implantation. [INCLUSION 2]	**[IEINC2]** Yes No
5.* ✔	Patient is a candidate for revision of all femoral and tibial components of a total knee replacement. [INCLUSION 3]	**[IEINC3]** Yes No
6.* ✔	Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation. [INCLUSION 4]	**[IEINC4]** Yes No

Exclusion Criteria [IE_S3]

**All of the below must be answered "No" for the patient to be included in the study.

7.* ✔	Patient has a Body Mass Index (BMI) > 40. [EXCLUSION 1]	**[IEEXC1]** Yes No
8.* ✔	Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation. [EXCLUSION 2]	**[IEEXC2]** Yes No
9.* ✔	Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device. [EXCLUSION 3]	**[IEEXC3]** Yes No
10.* ✔	Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's Disease) leading to progressive bone deterioration. [EXCLUSION 4]	**[IEEXC4]** Yes No
11.* ✔	Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days). [EXCLUSION 5]	**[IEEXC5]** Yes No
12.* ✔	Patient has a failed unicondylar knee prosthesis [EXCLUSION 6]	**[IEEXC6]** Yes No
13.* ✔	Patient has a known sensitivity to device materials. [EXCLUSION 7]	**[IEEXC7]** Yes No
14.* ✔	Patient is a prisoner. [EXCLUSION 8]	**[IEEXC8]** Yes No

COMMENTS [IE_S4]

15. ✔	Comments [Comments]	**[IECMT]** A200

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

TriathCone: Demographics (DM) [DM]

Demographics [DM]

1.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
2.	Subject Number *[read-only]* [Subj Number]	**[SUBID]** A10
3.* ✔	Subject Initials [Subj Initials]	**[INITIALS]** A3
4.* ✔	Education Level [Education Level]	**[EDU]** Less Than High School High School Diploma Greater Than High School
5.* ✔	Annual household income (Please choose one) [Annual household income]	**[INCOME]** <= $24,999 $25,000-$49,999 $50,000-$74,999 $75,000-$99,999 $100,000-$149,999 >= $150,000
6.* ✔	Employment Status [Employment Status]	**[EMPLOY]** Working Not Working
7.* ✔	Ethnicity [Ethnicity]	**[ETH]** Hispanic or Latino origin Not Hispanic or Latino origin
8.* ✔	Race [Race]	**[RACE]** American Indian or Alaskan Native Asian Black or African Native Hawaiian or other Pacific Islander White
If the subject is a current or past cigar and /or pipe smoker, please select "Non-smoker" and enter a comment below.		
9.* ✔	Cigarette Use [Cigarette Use]	**[CIGUSE]** Non-smoker **[cmpCURSMOK]** Current cigarette smoker **[KNPACK]** Does the subject know the number of packs/day? **[PACKS]** #Packs/Day xxx. Unknown **[KNYRSMOK]** Does the subject know the number of years he/she has been smoking? **[YRSMOK]** #Years xxx. Unknown **[cmpEXSMOK]** Ex-cigarette smoker **[KNEXPACK]** Does the subject know the number of packs/day? **[EXPACKS]** #Packs/Day xxx. Unknown **[KNEXYRSM]** Does the subject know the number of years he/she had been smoking? **[EXYRSMOK]** #Years xxx. Unknown **[STOPSM]** Date Stopped Req/Unk / Req/Unk / Req (1900-2025)
10.* ✔	Alcohol Use [Alcohol Use]	**[ALUSE]** Have never had alcohol Have not had alcohol in the last year Less than 3 drinks a week 3 - 7 drinks a week 8 - 14 drinks a week 15+ drinks a week
11.* ✔	Date of Birth [Date of Birth]	**[BRTHDAT]** Req / Req / Req (1900-2010)
12.*	Gender	**[GENDER]**

✔	[Gender]	○ Male ○ Female
13.* ✔	Height [Height]	**[HT]** xxxxx. ○ inches [b] ○ centimeters
14.* ✔	Weight [Weight]	**[WT]** xxxxx. ○ lbs [b] ○ kg
15.	BMI *[read-only]* [BMI]	**[BMI]** xxxxxxx.
16.* ✔	Primary Orthopedic diagnosis [Primary Orthopedic diagnosis]	**[INDX]** ○ Osteoarthritis ○ Traumatic Arthritis ○ Avascular Necrosis ○ **[cmpOTHDX]** Other **[OTHDX]** (Specify) A100
17.* ✔	Does the subject have any of the following conditions [Does subject have conditions]	**[MORBIDYN]** ○ **[cmpCMORBID]** Yes **[COMORBID]** ☐ Myocardial infarction ☐ Congestive heart failure ☐ Peripheral vascular disease ☐ Cerebrovascular disease ☐ Dementia ☐ Chronic pulmonary disease ☐ Connective tissue disease ☐ Peptic ulcer disease ☐ Mild liver disease ☐ Diabetes without organ damage ☐ Diabetes with organ damage ☐ Hemiplegia or paraplegia ☐ Moderate or severe renal disease ☐ Malignant tumor (any) ☐ Leukemia ☐ Lymphoma ☐ Moderate or severe liver disease ☐ Metastatic solid tumor ☐ HIV ○ No
18.* ✔	Concurrent Medical Conditions [Concurrent Medical Conditions]	**[CMCYN]** ○ **[cmpCMC]** Yes **[CMC]** ☐ **[cmpCA]** Cancer **[CANCER]** A200 ☐ **[cmpCARD]** Cardiovascular **[CARDIO]** A200 ☐ **[cmpDERM]** Dermatologic **[DERM]** A200 ☐ **[cmpDIG]** Digestive **[DIGEST]** A200 ☐ **[cmpENDO]** Endocrine / Metabolic **[ENDO]** A200

		[cmpIMM] Immunologic / Lymphatic **[IMM]** A200 **[cmpMUS]** Musculoskeletal **[MUS]** A200 **[cmpNEUR]** Neurologic **[NEUR]** A200 **[cmpPSYC]** Psychologic **[PSYC]** A200 **[cmpRESP]** Respiratory **[RESP]** A200 **[cmpSUBD]** Substance Dependence **[SUBD]** A200 **[cmpUROG]** Urogenital **[URO]** A200 **[cmpOTCMC]** Other **[OTCM]** (Specify) A200 No
Comments [DM_S5]		
19. ✔	Comments [Comments]	**[DMCOM]** A200
20.	Charlson-Deyo Comorbidity Index *[read-only]* [CCI]	**[CCI]** N2

Key: [✔] = Source verification required [b] = Base Unit [ ] = Item is collapsible

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TriathCone: CENSOR (CENSOR) [CENSOR]

CENSOR [CENSOR]

1.	Censor from Analysis *[hidden]* [Censor from Analysis]	**[CENSORFA]** **[cmpCENSOR]** Yes **[CNSRDT]** Date Censored Req / Req / Req (2015-2025) **[CNSREASN]** Censor Reason A200 No

Key: [*] = Item is required [✔] = Source verification required
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TriathCone: Knee Society Score: Pre-Op (PREKSS2011) [PREKSS2011]		
1.* ✔	Visit Date [Visit Date]	**[KSSDOV]** Req / Req / Req (2015-2025)
2.* ✔	Charnley Functional Classification [Charnley Functional Classification]	**[CHARNLY]** A Unilateral Knee Arthritis B1 Unilateral TKA, opposite knee arthritic B2 Bilateral TKA C1 TKR, but remote arthritis affecting ambulation C2 TKR, but medical condition affecting ambulation C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR
Objective Knee Indicators [PREKSS_S2]		
3.* ✔	Alignment: measured on AP standing Xray (Anatomic Alignment) [Alignment]	**[ALIGNMSR]** Neutral: 2-10 degrees valgus Varus: < 2 degrees valgus Valgus: > 10 degrees valgus
4.* ✔	Medial / Lateral instability: measured in full extension [Medial / Lateral instability]	**[INSTML]** None Little or < 5 mm Moderate or 5 mm Severe or > 5 mm
5.* ✔	Anterior / Posterior Instability: measured at 90 degrees [Anterior / Posterior Instability]	**[INSTAP]** None Moderate < 5 mm Severe > 5 mm
6.* ✔	Range of motion [Range of motion]	**[ROM]** N3
7.* ✔	Flexion Contracture [Flexion Contracture]	**[FLEXC]** None 1-5 degrees 6-10 degrees 11-15 degrees > 15 degrees
8.* ✔	Extensor Lag [Extensor Lag]	**[EXTLAG]** None < 10 degrees 10-20 degrees > 20 degrees
Symptoms [PREKSS_S3]		
9.* ✔	Pain with level walking [Pain with level walking]	**[PNLVLWLK]** 0 - None 1 2 3 4 5 6 7 8 9 10 - Severe
10.* ✔	Pain with stairs or inclines [Pain with stairs or inclines]	**[PNSTAIR]** 0 - None 1 2 3 4 5 6 7 8 9 10 - Severe
11.* ✔	Does this knee feel "Normal" to you? [Knee feels Normal]	**[FEELNORM]** Always Sometimes Never
Subject Satisfaction [PREKSS_S4]		
12.* ✔	Currently, how satisfied are you with the pain level of your knee while sitting? [Satisfied with pain level of knee while sitting]	**[SIT]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
13.* ✔	Currently, how satisfied are you with the pain level of your knee while lying in bed? [Satisfied with pain level of knee while lying in bed]	**[INBED]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
14.* ✔	Currently, how satisfied are you with your knee function while getting out of bed? [Satisfied with your knee function while getting out of bed]	**[OUTBED]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
15.* ✔	Currently, how satisfied are you with your knee function while performing light household duties? [Satisfied with your knee function while performing light household duties]	**[HSEHLD]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
16.* ✔	Currently, how satisfied are you with your knee function while performing leisure recreational activities? [Satisfied with your knee function while performing leisure recreational activities]	**[RECACT]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
Subject Expectations [PREKSS_S5]		
What do you expect to accomplish with your knee replacement:		
17.* ✔	Do you expect your knee joint replacement surgery will relieve your knee pain? [Expect knee joint replacement surgery will relieve knee pain]	**[JNTRPLC]** No, not at all Yes, a little bit Yes, somewhat Yes, a moderate amount Yes, a lot
18.* ✔	Do you expect your surgery will help you carry out your normal activities of daily living? [Expect surgery will help you carry out normal activities of daily living]	**[DAILYACT]** No, not at all Yes, a little bit Yes, somewhat

		○ Yes, a moderate amount ○ Yes, a lot
19.* ✔	Do you expect your surgery will help you perform leisure, recreational or sports activities? [Expect surgery will help you perform leisure, recreational or sports activities]	**[LSRACT]** ○ No, not at all ○ Yes, a little bit ○ Yes, somewhat ○ Yes, a moderate amount ○ Yes, a lot
Functional Activities [PREKSS_S6]		
20.* ✔	Can you walk without any aids (such as a cane, crutches or wheelchair)? [Walk without any aids?]	**[WALKAID]** ○ Yes ○ **[cmpWALKAID]** ⊟ No **[OTWLKAID]** If no, which of the following aid(s) do you use? ○ Wheelchair ○ Walker ○ Crutches ○ Two canes ○ One crutch ○ One cane ○ Knee sleeve / brace **[KNEEAIDS]** Do you use these aid(s) because of your knees? ○ Yes ○ No
21.* ✔	For how long can you stand (with or without aid) before sitting due to knee discomfort? [How long stand before sitting?]	**[HLSTAND]** ○ Cannot stand ○ 0-5 minutes ○ 6-15 minutes ○ 16-30 minutes ○ 31-60 minutes ○ More than an hour
22.* ✔	For how long can you walk (with or without aid) before stopping due to knee discomfort? [How long walk before stopping?]	**[HLWALK]** ○ Cannot walk ○ 0-5 minutes ○ 6-15 minutes ○ 16-30 minutes ○ 31-60 minutes ○ More than an hour
How much does your knee bother you during each of the following activities? [PREKSS_S10]		
23.* ✔	Walking on an uneven surface [Walk on uneven surface]	**[UNEVEN]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
24.* ✔	Turning or pivoting on your leg [Turn or pivot leg]	**[PIVOT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
25.* ✔	Climbing up or down a flight of stairs [Climb up down stairs]	**[UPDN]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
26.* ✔	Getting up from a low couch or a chair without arms [Up from low couch or chair without arms]	**[GETUP]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
27.* ✔	Getting into or out of a car [Get into or out of a car]	**[CARINOUT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
28.* ✔	Moving laterally (stepping to the side) [Move laterally]	**[MOVLAT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
29.* ✔	Climbing a ladder or step stool [Climb ladder or step stool]	**[CLIMB]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
30.* ✔	Carrying a shopping bag for a block [Carry bag for a block]	**[CARRY]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
31.* ✔	Squatting [Squatting]	**[SQUAT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
32.* ✔	Kneeling [Kneeling]	**[KNEELING]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
33.* ✔	Running [Running]	**[RUNNING]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
Discretionary Knee Activities [PREKSS_S9]		
34.* ✔	Discretionary Knee Activity 1 [Discretionary Knee Activity 1]	**[cmpDISCACT1]** **[DISCACT1]** Discretionary Knee Activities

		[cl_DISCACT] **[BOTHER1]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
35.* ✔	Discretionary Knee Activity 2 [Discretionary Knee Activity 2]	**[cmpDISCACT2]** **[DISCACT2]** Discretionary Knee Activities [cl_DISCACT] **[BOTHER2]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
36.* ✔	Discretionary Knee Activity 3 [Discretionary Knee Activity 3]	**[cmpDISCACT3]** **[DISCACT3]** Discretionary Knee Activities [cl_DISCACT] **[BOTHER3]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
37.	Alignment *[read-only]* [Alignment]	**[ALIGNSC]** xxxxxxx.
38.	Instability *[read-only]* [Instability]	**[INSTSC]** xxxxxxx.
39.	Joint Motion *[read-only]* [Joint Motion]	**[JOINTSC]** xxxxxxx.
40.	Symptoms *[read-only]* [Symptoms]	**[SYMPSC]** xxxxxxx.
41.	Subject Satisfaction Score *[read-only]* [Subject Satisfaction Score]	**[SATSC]** xxxxxxx.
42.	Subject Expectations *[read-only]* [Subject Expectations]	**[EXPSC]** xxxxxxx.
43.	Walking and Standing *[read-only]* [Walking and Standing]	**[WLKSTSC]** xxxxxxx.
44.	Standard Activities *[read-only]* [Standard Activities]	**[STDACTSC]** xxxxxxx.
45.	Advanced Activities *[read-only]* [Advanced Activities]	**[ADVACTSC]** xxxxxxx.
46.	Discretionary Knee Activities *[read-only]* [Discretionary Knee Activities]	**[DISC]** xxxxxxx.
47.	Objective Knee Score *[read-only]* [Objective Knee Score]	**[OBJKSC]** xxxxxxx.
48.	Functional Knee Score *[read-only]* [Functional Knee Score]	**[FUNKSC]** xxxxxxx.

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TriathCone: SF-12v2 Health Survey (SF12) [SF12]

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark the circle that best describes your answer.

1.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
1) In general, would you say your health is: [SF12new_S1]		
2.* ✔	In general, would you say your health is: [In general, would you say your health is]	**[SFHEALTH]** Excellent Very Good Good Fair Poor
2) 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? [SF12new_S2]		
3.* ✔	a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf [Moderate activities]	**[MOD]** Yes, limited a lot Yes, limited a little No, not limited at all
4.* ✔	b. Climbing several flights of stairs [Climbing stairs]	**[STAIR]** Yes, limited a lot Yes, limited a little No, not limited at all
3) 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? [SF12new_S3]		
5.* ✔	a. Accomplished less than you would like [Accomplished less]	**[SFACCOM]** All of the time Most of the time Some of the time A little of the time None of the time
6.* ✔	b. Were limited in the kind of work or other activities [Limited in kind of work or activities]	**[SFKIND]** All of the time Most of the time Some of the time A little of the time None of the time
4) 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)? [SF12new_S4]		
7.* ✔	a. Accomplished less than you would like [Accomplished less]	**[SFACCLESS]** All of the time Most of the time Some of the time A little of the time None of the time
8.* ✔	b. Did work or activities less carefully than usual [Did work or activities less carefully]	**[SFUSUAL]** All of the time Most of the time Some of the time A little of the time None of the time
5) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? [SF12new_S5]		
9.* ✔	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? [Pain affect normal work]	**[SFPAIN]** Not at all A little bit Moderately Quite a bit Extremely
6) 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... [SF12new_S6]		
10.* ✔	a. Have you felt calm and peaceful? [Felt calm peaceful]	**[SFPEACE]** All of the time Most of the time Some of the time A little of the time None of the time
11.* ✔	b. Did you have a lot of energy? [Have a lot of energy]	**[SFENRGY]** All of the time Most of the time Some of the time A little of the time None of the time
12.* ✔	c. Have you felt downhearted and depressed? [Felt downhearted and depressed?]	**[SFDEPRES]** All of the time Most of the time Some of the time A little of the time None of the time
7) 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.)? [SF12new_S7]		
13.* ✔	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.)? [Physical health or emotion interfer social]	**[SFPHYHLTH]** All of the time Most of the time Some of the time A little of the time None of the time
14.	PHYSICAL COMPONENT SCORE *[read-only]* [PHYSICAL COMPONENT SCORE]	**[SF12PCS]** xxxxxxxxxx.
15.	MENTAL COMPONENT SCORE *[read-only]* [MENTAL COMPONENT SCORE]	**[SF12MCS]** xxxxxxxxxx.
16.	Physical Functioning *[read-only]* [Physical Functioning]	**[PF]** xxxxxxxxxx.
17.	Role Physical *[read-only]* [Role Physical]	**[RP]** xxxxxxxxxx.
18.	Bodily Pain *[read-only]* [Bodily Pain]	**[BP]** xxxxxxxxxx.

19.	General Health *[read-only]* [General Health]	**[GH]** xxxxxxxxxx.
20.	Vitality *[read-only]* [Vitality]	**[VT]** xxxxxxxxxx.
21.	Social Functioning *[read-only]* [Social Functioning]	**[SF]** xxxxxxxxxx.
22.	Role Emotional *[read-only]* [Role Emotional]	**[RE]** xxxxxxxxxx.
23.	Mental Health *[read-only]* [Mental Health]	**[MH]** xxxxxxxxxx.

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TriathCone: Lower Extremity Activity Scale (LEAS) [LEAS]

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

1.* ✔	Lower Extremity Activity Scale [Lower Extremity Activity Scale]	**[LEASCALE]** 1. I am confined to bed all day 2. I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc.). 3. I am either in bed or sitting in a chair most of the day. 4. I sit most of the day, except for minimal transfer activities, no walking or standing. 5. 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.) 6. 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. 7. I walk around my house and go outside at will, walking one or two blocks at a time. 8. I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting). 9. 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). 10a. I am up and about at will in my house and outside. I also work outside the house in a minimally active job. 10b. I am up and about at will in my house and outside. I also work outside the house in a moderately active job. 10c. I am up and about at will in my house and outside. I also work outside the house in a extremely active job. 11a. I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming occasionally (2-3 times per month). 11b. I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming 2-3 times per week. 11c. I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming daily. 12a. I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports occasionally (2-3 times per month). 12b. I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports 2-3 times per week. 12c. I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports daily.
2.	LEAS SCORE *[read-only]* [LEAS SCORE]	**[LEASCOR]** N2
3.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
4. ✔	Comments [Comments]	**[LEASCMT]** A200

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TriathCone: HSS Patella Score (HSSPAT) [HSSPAT]

Patient Questionnaire [HSSPAT_S1]

1.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
2.* ✔	Rate the pain you experience on the front of your knee while rising from a low chair [Pain front of knee rising from low chair]	**[RATEPAIN]** N2 (0 - 10)
Do you feel that the anterior (front) part of your knee is limiting you while [HSSPAT_S2]		
3.* ✔	Climbing stairs? [Climbing stairs]	**[CLIMSTAIR]** Yes No
4.* ✔	Descending stairs? [Descending stairs]	**[DESSTAIR]** Yes No
5.* ✔	Sitting for prolonged time (30 minutes at 90 degrees)? [Prolonged sitting]	**[LONGSIT]** Yes No
For Surgeon's Use Only [HSSPAT_S3]		
6.* ✔	Tenderness with palpation of medial and/or lateral patellar retinaculum-facet? [Tenderness with palpation]	**[TENDER]** Absent Present
7.* ✔	Crepitus during active range of motion (ROM)? [Crepitus]	**[CREP]** None Mild (for a limited ROM) Moderate (through entire ROM) Severe (catching/clunk)
8.* ✔	Quadriceps Strength [Quadriceps Strength]	**[QUAD]** Normal (5/5) Reduced (3-4/5) Deficient (1-2/5)
9. ✔	Comments [Comments]	**[HSSPATCM]** A200
10.	HSS Patella Score *[read-only]* [HSS Patella Score]	**[PATSCOR]** N3

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TriathCone: EQ-5D Health Questionnaire (EQ5D) [EQ5D]

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

1.* ✔	Mobility [Mobility]	**[MOBIL]** I have no problems in walking about I have some problems in walking about I am confined to bed
2.* ✔	Self-Care [SelfCare]	**[SELFCARE]** I have no problems with self-care I have some problems washing or dressing myself I am unable to wash or dress myself
3.* ✔	Usual Activities (e.g. work, study, housework, family or leisure activities) [Usual Activities]	**[UNACT]** I have no problems with performing my usual activities I have some problems with performing my usual activities I am unable to perform my usual activities
4.* ✔	Pain/Discomfort [PainDiscomfort]	**[EQ5DPD]** I have no pain or discomfort I have moderate pain or discomfort I have extreme pain or discomfort
5.* ✔	Anxiety/Depression [AnxietyDepression]	**[EQ5DAD]** I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed
6.* ✔	EQ VAS SCORE [EQ VAS SCORE]	**[EQVAS]** N3
7.	TTO Score *[read-only]* [TTO Score]	**[EQ5DTTO]** xxxxxxx.
8.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
9. ✔	Comments [Comments]	**[EQ5DCMT]** A200

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TriathCone: End of Stem Pain (ESP) [ESP]		
1.* ✔	Date of Assessment [Date of Assessment]	**[DOA]** Req / Req / Req (2015-2025)
2.* ✔	Shin Pain [Shin Pain]	**[SHINPAIN]** No Pain **[cmpSHIN1]** Pain with Extreme Activity Only **[SHINLOC1]** Proximal Mid-Shaft Distal **[cmpSHIN2]** Pain with Moderate Activity **[SHINLOC2]** Proximal Mid-Shaft Distal **[cmpSHIN3]** Pain with Normal Activity **[SHINLOC3]** Proximal Mid-Shaft Distal **[cmpSHIN4]** Pain at Rest **[SHINLOC4]** Proximal Mid-Shaft Distal
3.* ✔	Thigh Pain [Thigh Pain]	**[THIPAIN]** No Pain **[cmpTHI1]** Pain with Extreme Activity Only **[THILOC1]** Proximal Distal **[cmpTHI2]** Pain with Moderate Activity **[THILOC2]** Proximal Distal **[cmpTHI3]** Pain with Normal Activity **[THILOC3]** Proximal Distal **[cmpTHI4]** Pain at Rest **[THILOC4]** Proximal Distal
4.* ✔	Does pain pertain to the operative side? [Pain pertain to operative side]	**[PAINOPS]** Yes No
5. ✔	Comments [Comments]	**[ESPCMT]** A200

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TriathCone: Previous Implant Information (PIF) [PIF]

Diagnosis [PIF_S1]

1.* ✔	Visit Date [Visit Date]	**[PIFDOV]** Req / Req / Req (2015-2025)
2.* ✔	For the TKR being revised, provide Date of Implant [TKR Date of Implant]	**[IMPDT]** Req/Unk / Req/Unk / Req (1980-2025)
3.* ✔	Type of existent implant [Type of existent implant]	**[IMPTYP]** ☐ Posterior Cruciate Retaining ☐ Posterior Cruciate Substituting ☐ Constrained Condylar ☐ Rotating Hinge
4.* ✔	Number of previous total joint surgeries to operative knee [Num previous total joint surgeries to operative knee]	**[NUMSURG]** ○ 1 ○ 2 ○ 3 ○ **[cmpSURGSP]** > 3 **[SURGSP]** Specify N1

Prosthesis [PIF_S2]

5.* ✔	Tibial Baseplate [Tibial Baseplate]	**[BASEPL]** ○ Cemented ○ Cementless
6.* ✔	Femoral Component [Femoral Component]	**[FCOMP]** ○ Cemented ○ Cementless
7.* ✔	Implant Manufacturer of tibial & femoral components [Implant Manufacturer of tibial & femoral components]	**[TFMANU]** ○ Biomet ○ Depuy / J&J ○ Smith & Nephew ○ Stryker ○ Wright ○ Zimmer ○ **[cmpTFMANU]** Other **[OTFMANU]** Specify A30
8.* ✔	Patellar Component [Patellar Component]	**[PCOMP]** ○ **[cmpPMANU1]** Cemented **[PMANU1]** Patellar Implant Manufacturer ○ Biomet ○ Depuy / J&J ○ Smith & Nephew ○ Stryker ○ Wright ○ Zimmer ○ **[cmpOTPCOMP1]** Other **[OTPCOMP1]** Specify A30 ○ **[cmpPMANU2]** Cementless **[PMANU2]** Patellar Implant Manufacturer ○ Biomet ○ Depuy / J&J ○ Smith & Nephew ○ Stryker ○ Wright ○ Zimmer ○ **[cmpOTPCOMP2]** Other **[OTPCOMP2]** Specify A30 ○ Not Revised

Reason for Revision [PIF_S3]

9.* ✔	Type of Failure [Type of Failure]	**[FAILTYP]** ○ Aseptic failure of the knee ○ Septic failure of the knee

Reason for Revision [PIF_S4]

10.* ✔	Reason for Revision [Reason for Revision]	**[REVREAS]** ☐ **[cmpFALIKNEE]** Failed Total Knee **[FAILKNEE]** ☐ Failed femoral component ☐ Failed tibial component ☐ Failed patellar component

		☐ Failed polyethylene insert ☐ Polyethylene wear ☐ Global instability ☐ Extension instability ☐ Mid-Flexion instability ☐ Flexion instability ☐ Infection ☐ **[cmpOTFAIL]** Other Implant Failure **[OTFAIL]** ☐ Ingrowth bead shedding ☐ Ingrowth pad dissociation ☐ Breakage of wires / screws ☐ Breakage of implant ☐ Modular component dissociation ☐ Metal wear ☐ Malalignment ☐ Pain ☐ Arthrofibrosis ☐ **[cmpMIGRA]** Implant Migration, Loosening **[MIGRA]** ☐ Implant migration, loosening, femoral ☐ Implant migration, loosening, tibial ☐ Implant migration, loosening, patellar ☐ **[cmpLYSIS]** Bone Lysis **[LYSIS]** ☐ Bone lysis, femoral ☐ Bone lysis, tibial ☐ Bone lysis, patellar ☐ **[cmpGRFAIL]** Bone Graft Failure **[GRFAIL]** ☐ Bone graft, non-union ☐ Bone graft, collapse / extrusion ☐ Bone graft, resorption ☐ Bone graft, fracture ☐ **[cmpOTREV]** Other **[OTREV]** Specify A200
11. ✔	Comments [Comments]	**[PIFCMT]** A200

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TriathCone: Surgical Details (SURG) [SURG]		
1.* ✔	Surgery Date [Surgery Date]	**[SURGDT]** Req / Req / Req (2015-2025)
2.* ✔	Type of Anesthesia Used [Type of Anesthesia Used]	**[ANESTYP]** ☐ General ☐ Spinal ☐ Epidural ☐ Femoral Block
3.* ✔	Surgical Approach [Surgical Approach]	**[APPROACH]** ○ Medial Parapatellar ○ Lateral Parapatellar ○ Sub Vastus ○ Mid Vastus
4.* ✔	Joint Line Position Prior to Implant Removal: Full Extension [Joint Line Position Prior to Implant Removal: Full Extension]	**[PRIORFULL]** N4 mm[b]
5.* ✔	Joint Line Position Prior to Implant Removal: 90 degree Flexion [Joint Line Position Prior to Implant Removal: 90 degree Flexion]	**[PRIOR90]** N4 mm[b]
6.* ✔	Joint Line Position Final Triathlon Cone implanted: Full Extension [Joint Line Position Final Triathlon Cone implanted: Full Extension]	**[FINALFULL]** N4 mm[b]
7.* ✔	Joint Line Position Final Triathlon Cone implanted: 90 degree Flexion [Joint Line Position Final Triathlon Cone implanted: 90 degree Flexion]	**[FINAL90]** N4 mm[b]
8.* ✔	Tibial AORI Classification [Tibial AORI]	**[TAORI]** ○ Type I ○ Type IIa ○ Type IIb ○ Type III
9.* ✔	Femoral AORI Classification [Femoral AORI]	**[FAORI]** ○ Type I ○ Type IIa ○ Type IIb ○ Type III
10.* ✔	Navigation Used [Navigation Used]	**[NAVIGATION]** ○ Yes ○ No
11.* ✔	Estimated blood loss [Estimated blood loss]	**[BLOSS]** N4 cc's
12.* ✔	Units of blood transfused [Units of blood transfused]	**[UNITRANS]** N4 cc's
13.* ✔	Skin to skin time [Skin to skin time]	**[SKTOSK]** N3 minutes
14.* ✔	Tourniquet time [Tourniquet time]	**[TOURN]** N3 minutes
15.* ✔	Tibio-Femoral Gap, Full Extension: Medial [Tibio-Femoral Gap, Full Extension: Medial]	**[GAPFLMED]** N2 mm[b]
16.* ✔	Tibio-Femoral Gap, Full Extension: Lateral [Tibio-Femoral Gap, Full Extension: Lateral]	**[GAPFLLAT]** N2 mm[b]
17.* ✔	Tibio-Femoral Gap, 90 degree Flexion: Medial [Tibio-Femoral Gap, 90 degree Flexion: Medial]	**[GAP90MED]** N2 mm[b]
18.* ✔	Tibio-Femoral Gap, 90 degree Flexion: Lateral [Tibio-Femoral Gap, 90 degree Flexion: Lateral]	**[GAP90LAT]** N2 mm[b]
19.* ✔	Tibial Bone Loss? [Tibial Bone Loss?]	**[BLOSSTIB]** ○ **[cmpTIBLOC]** ⊟ Yes **[TIBLOC]** ☐ **[cmpA]** ⊟ Anterior **[ACONTAIN]** Anterior defect contained ○ Yes ○ No ☐ **[cmpP]** ⊟ Posterior **[PCONTAIN]** Posterior defect contained ○ Yes ○ No ☐ **[cmpM]** ⊟ Medial **[MCONTAIN]** Medial defect contained ○ Yes ○ No ☐ **[cmpL]** ⊟ Lateral **[LCONTAIN]** Lateral defect contained ○ Yes ○ No ○ No

20.* ✔	Femoral Bone Loss? [Femoral Bone Loss?]	**[BLOSSFEM]** **[cmpFEMLOC]** Yes **[FEMLOC]** **[cmpAF]** Anterior Femur **[AFCONTAIN]** Anterior femur defect contained? Yes No **[cmpCC]** Central **[CCONTAIN]** Central defect contained? Yes No **[cmpMD]** Medial Distal Femur **[MDCONTAIN]** Medial Distal Femur defect contained? Yes No **[cmpLD]** Lateral Distal Femur **[LDCONTAIN]** Lateral Distal Femur defect contained? Yes No **[cmpLP]** Lateral Posterior Condyle **[LPCONTAIN]** Lateral Posterior Condyle defect contained? Yes No **[cmpMP]** Medial Posterior Condyle **[MPCONTAIN]** Medial Posterior Condyle defect contained? Yes No No
21.* ✔	Bone Removed: Distal Femur [Bone Removed: Distal Femur]	**[REMOVDF]** N3 mm[b]
22.* ✔	Bone Removed: Proximal Femur [Bone Removed: Proximal Femur]	**[REMOVDPF]** N3 mm[b]
23.* ✔	Distal Femoral Coverage [Distal Femoral Coverage]	**[DISTFMR]** Complete **[cmpUNSZ]** Undersized **[UNDERSZ]** N2 mm[b] **[cmpOVHG]** Overhang **[OVHANG]** N2 mm[b]
24.* ✔	Posterior Condyles: Overhanging bone removed prior to final implant? [Posterior Condyles: Overhang bone removed prior to final implant]	**[PCONDYL]** Yes No
25.* ✔	Proximal Tibia: AP Coverage Complete? [Proximal Tibia: AP Coverage Complete?]	**[APCOMP]** Yes **[UNOVAP]** No **[cmpANTPOS1]** Undersized **[ANTPOS1]** **[ANT1]** Anterior N2 mm[b] **[POS1]** Posterior N2 mm[b] **[cmpANTPOS2]** Overhang **[ANTPOS2]** **[ANT2]** Anterior N2 mm[b] **[POS2]** Posterior N2 mm[b]
26.* ✔	Proximal Tibia: ML Coverage Complete? [Proximal Tibia: ML Coverage Complete?]	**[MLCOMP]** Yes **[UNOVML]** No **[cmpMEDLAT1]** Undersized **[MEDLAT1]** **[MED1]** Medial N2 mm[b] **[LAT1]** Lateral N2 mm[b] **[cmpMEDLAT2]** Overhang **[MEDLAT2]** **[MED2]** Medial N2 mm[b] **[LAT2]** Lateral N2 mm[b]

27.* ✔	How satisfied are you with the fit? [How satisfied with fit]	**[SATFIT]** Extremely Quite a bit Moderately A little bit Not at all
28.* ✔	Intraoperative complication? (If yes, complete AE form.) [Intraoperative complication]	**[COMPL]** Yes No
29.* ✔	Post-op plan [Post-op plan]	**[POSTPLAN]** Full weight bearing Partial weight bearing
30.* ✔	Discharge to [Discharge to]	**[DISCHRG]** Skilled Nursing Facility Chronic Care Center Rehabilitation Unit Home **[cmpOTDIS]** Other **[OTDIS]** Specify A100
31.* ✔	Discharge Date [Discharge Date]	**[SDDISDT]** Req / Req / Req (2015-2025)
32.	Length of Hospital Stay *[read-only]* [Length of Hospital Stay]	**[STAY]** N3 Days[b]
33. ✔	Comments [Surgery Comments]	**[SURGCOM]** A200

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TriathCone: Surgical Prostheses (SP) [SP]

COMPONENT LISTING [SP_S1]

1.* ✔	Femoral Component [Femoral Component]	**[cmpFC]** **[FEMREF]** Femoral Component Reference # **[clFREF]** **[FEMLOT]** Femoral Component Lot # A50
2. ✔	Femoral Cone Augment [Femoral Cone Augment]	**[cmpFCA]** **[FCONEREF]** Femoral Cone Augment Reference # **[clFCREF]** **[FCONELOT]** Femoral Cone Augment Lot # A50
3.* ✔	Tibial Component/Metal Tray [Tibial Component/Metal Tray]	**[cmpTC]** **[TIBIREF]** Tibial Component/Metal Tray Reference # **[clTIBIREF]** **[TIBLOT]** Tibial Component/Metal Tray Lot # A50
4. ✔	Tibial Cone Augment [Tibial Cone Augment]	**[cmpTCA]** **[TCONEREF]** Tibial Cone Augment Reference # **[clTCREF]** **[TCONELOT]** Tibial Cone Augment Lot # A50
5.* ✔	Tibial Insert/UHMWPE Bearing [Tibial Insert/UHMWPE Bearing]	**[cmpTI]** **[BEARREF]** Tibial Insert/UHMWPE Bearing Reference # A10 **[BERLOT]** Tibial Insert/UHMWPE Bearing Lot # A50
6.* ✔	Patellar Component Revised? [Patellar Component Revised]	**[REVISED]** ◉ **[cmpPC]** Yes **[PATREF]** Patellar Component Reference # **[clPATREF]** **[PATLOT]** Patellar Component Lot # A50 ○ No

PROSTHESIS [SP_PROS]

7.* ✔	Ancillary Devices? (Stem extenders, offset adapters) [Ancillary Devices]	**[ANCILL]** ○ Yes ○ No

	Ancillary Devices	Reference #	Lot #
8. ✔			

Ancillary Devices Entry [SP_ANCIL]

8.1* ✔	Ancillary Devices? (Stem extenders, offset adapters) [Ancillary Devices]	**[ANCILDEV]** ○ Stem Extenders ○ Offset Adapters
8.2* ✔	Reference # [Reference #]	**[ANCILREF]** A10
8.3* ✔	Lot # [Lot #]	**[ANCILLOT]** A50

9.* ✔	Stem 1 [Stem 1]	**[cmpSTEM1]** **[STEMREF1]** Stem Reference #1 A10 **[STEMLOT1]** Stem Lot #1 A50
10. ✔	Stem 2 [Stem 2]	**[cmpSTEM2]** **[STEMREF2]** Stem Reference #2 A10 **[STEMLOT2]** Stem Lot #2 A50
11. ✔	Stem Area Cemented? [Stem Area Cemented]	**[STEMCEM]** ◉ **[cmpSTEMAREA]** Yes **[STEMAREA]** Stem Area ○ Proximal Portion ○ Distal Tip ○ Entire Stem

		○ No
12. ✔	If Tibial Offset Adapters used, complete the following [Tibial offset adapter: magnitude and orientation]	**[cmpOFFADTIB]** **[MAGTIB]** Magnitude N1 **[ORIENTT]** Orientation N2
13. ✔	If Femoral Offset Adapters used, complete the following [Femoral offset adapters: magnitude and orientation]	**[cmpOFFADDFEM]** **[MAGFEM]** Magnitude N1 **[ORIENTF]** Orientation N2
14.* ✔	Augmentation Used? (Non-cone augments, femoral locking screws, bone grafts, etc.) [Augmentation Used]	**[AUGUSEYN]** ○ Yes ○ No

	Augmentation	Reference #	Lot #
15. ✔			

Augmentation Entry [SP_AUG]

15.1* ✔	Augmentation [Augmentation]	**[AUGMEN]** ○ Tibial Augment ○ Femoral Augment ○ Femoral Locking Screw ○ Bone Graft ○ **[cmpOTAUG]** ⊟ Other **[OTAUG]** Specify A200
15.2* ✔	Reference # [Reference #]	**[AUGREF]** A10
15.3* ✔	Lot # [Lot #]	**[AUGLOT]** A50

COMMENTS [SP_COM]

16. ✔	Comments [Surgical Prostheses Comments]	**[SPCOM]** A200

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TriathCone: Knee Society Score: Post-Op (POSTKSS2011) [POSTKSS2011]		
1.* ✔	Visit Date [Visit Date]	**[KSSDOV]** Req / Req / Req (2015-2025)
2.* ✔	Height [Height]	**[HT]** xxxxx. inches [b] centimeters
3.* ✔	Weight [Weight]	**[WT]** xxxxx. lbs [b] kg
4.	BMI *[read-only]* [BMI]	**[BMI]** xxxxxxx.
5.* ✔	Charnley Functional Classification [Charnley Functional Classification]	**[CHARNLY]** A Unilateral Knee Arthritis B1 Unilateral TKA, opposite knee arthritic B2 Bilateral TKA C1 TKR, but remote arthritis affecting ambulation C2 TKR, but medical condition affecting ambulation C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR
Objective Knee Indicators [POSTKSS_S2]		
6.* ✔	Alignment: measured on AP standing Xray (Anatomic Alignment) [Alignment]	**[ALIGN]** Neutral: 2-10 degrees valgus Varus: < 2 degrees valgus Valgus: > 10 degrees valgus
7.* ✔	Medial / Lateral instability: measured in full extension [Medial / Lateral instability]	**[INSTML]** None Little or < 5 mm Moderate or 5 mm Severe or > 5 mm
8.* ✔	Anterior / Posterior Instability: measured at 90 degrees [Anterior / Posterior Instability]	**[INSTAP]** None Moderate < 5 mm Severe > 5 mm
9.* ✔	Range of motion [Range of motion]	**[ROM]** N3
10.* ✔	Flexion Contracture [Flexion Contracture]	**[FLEXC]** None 1-5 degrees 6-10 degrees 11-15 degrees > 15 degrees
11.* ✔	Extensor Lag [Extensor Lag]	**[EXTLAG]** None < 10 degrees 10-20 degrees > 20 degrees
Symptoms [POSTKSS_S3]		
12.* ✔	Pain with level walking [Pain with level walking]	**[PNLVLWLK]** 0 - None 1 2 3 4 5 6 7 8 9 10 - Severe
13.* ✔	Pain with stairs or inclines [Pain with stairs or inclines]	**[PNSTAIR]** 0 - None 1 2 3 4 5 6 7 8 9 10 - Severe
14.* ✔	Does this knee feel "Normal" to you? [Knee feels Normal]	**[FEELNORM]** Always Sometimes Never
Subject Satisfaction [POSTKSS_S4]		
15.* ✔	Currently, how satisfied are you with the pain level of your knee while sitting? [Satisfied with pain level of knee while sitting]	**[SIT]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
16.* ✔	Currently, how satisfied are you with the pain level of your knee while lying in bed? [Satisfied with pain level of knee while lying in bed]	**[INBED]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
17.* ✔	Currently, how satisfied are you with your knee function while getting out of bed? [Satisfied with your knee function while getting out of bed]	**[OUTBED]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
18.* ✔	Currently, how satisfied are you with your knee function while performing light household duties? [Satisfied with your knee function while performing light household duties]	**[HSEHLD]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
19.* ✔	Currently, how satisfied are you with your knee function while performing leisure recreational activities? [Satisfied with your knee function while performing leisure recreational activities]	**[RECACT]** Very Satisfied Satisfied Neutral Dissatisfied Very Dissatisfied
Subject Expectations [POSTKSS_S5]		
Compared to what you expected before your knee replacement:		
20.* ✔	My expectations for pain relief were... [My expectations for pain relief were]	**[EXPPR]** Too High - "I'm a lot worse than I thought" Too High - "I'm somewhat worse than I thought"

		○ Just Right - "My expectations were met" ○ Too Low - "I'm somewhat better than I thought" ○ Too Low - "I'm a lot better than I thought"
21.* ✔	My expectations for being able to do my normal activities of daily living were... [My expectations for being able to do my normal activities of daily living were...]	**[EXPNORM]** ○ Too High - "I'm a lot worse than I thought" ○ Too High - "I'm somewhat worse than I thought" ○ Just Right - "My expectations were met" ○ Too Low - "I'm somewhat better than I thought" ○ Too Low - "I'm a lot better than I thought"
22.* ✔	My expectations for being able to do my leisure, recreational or sports activities were... [My expectations for being able to do my leisure, recreational or sports activities were...]	**[EXPLSRE]** ○ Too High - "I'm a lot worse than I thought" ○ Too High - "I'm somewhat worse than I thought" ○ Just Right - "My expectations were met" ○ Too Low - "I'm somewhat better than I thought" ○ Too Low - "I'm a lot better than I thought"
Functional Activities [POSTKSS_S6]		
23.* ✔	Can you walk without any aids (such as a cane, crutches or wheelchair)? [Walk without any aids?]	**[WALKAID]** ○ Yes ○ **[cmpWALKAID]** ⊟ No **[OTWLKAID]** If no, which of the following aid(s) do you use? ○ Wheelchair ○ Walker ○ Crutches ○ Two canes ○ One crutch ○ One cane ○ Knee sleeve / brace **[KNEEAIDS]** Do you use these aid(s) because of your knees? ○ Yes ○ No
24.* ✔	For how long can you stand (with or without aid) before sitting due to knee discomfort? [How long stand before sitting?]	**[HLSTAND]** ○ Cannot stand ○ 0-5 minutes ○ 6-15 minutes ○ 16-30 minutes ○ 31-60 minutes ○ More than an hour
25.* ✔	For how long can you walk (with or without aid) before stopping due to knee discomfort? [How long walk before stopping?]	**[HLWALK]** ○ Cannot walk ○ 0-5 minutes ○ 6-15 minutes ○ 16-30 minutes ○ 31-60 minutes ○ More than an hour
How much does your knee bother you during each of the following activities? [POSTKSS_S10]		
26.* ✔	Walking on an uneven surface [Walk on uneven surface]	**[UNEVEN]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
27.* ✔	Turning or pivoting on your leg [Turn or pivot leg]	**[PIVOT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
28.* ✔	Climbing up or down a flight of stairs [Climb up down stairs]	**[UPDN]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
29.* ✔	Getting up from a low couch or a chair without arms [Up from low couch or chair without arms]	**[GETUP]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
30.* ✔	Getting into or out of a car [Get into or out of a car]	**[CARINOUT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
31.* ✔	Moving laterally (stepping to the side) [Move laterally]	**[MOVLAT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
32.* ✔	Climbing a ladder or step stool [Climb ladder or step stool]	**[CLIMB]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
33.* ✔	Carrying a shopping bag for a block [Carry bag for a block]	**[CARRY]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
34.* ✔	Squatting [Squatting]	**[SQUAT]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this
35.* ✔	Kneeling [Kneeling]	**[KNEELING]** ○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

36.* ✔	Running [Running]	**[RUNNING]** No bother / Slight / Moderate / Severe / Very severe / Cannot do (because of knee) / I never do this
Discretionary Knee Activities [POSTKSS_S9]		
37.* ✔	Discretionary Knee Activity 1 [Discretionary Knee Activity 1]	**[cmpDISCACT1]** **[DISCACT1]** Discretionary Knee Activities **[cl_DISCACT]** **[BOTHER1]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
38.* ✔	Discretionary Knee Activity 2 [Discretionary Knee Activity 2]	**[cmpDISCACT2]** **[DISCACT2]** Discretionary Knee Activities **[cl_DISCACT]** **[BOTHER2]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
39.* ✔	Discretionary Knee Activity 3 [Discretionary Knee Activity 3]	**[cmpDISCACT3]** **[DISCACT3]** Discretionary Knee Activities **[cl_DISCACT]** **[BOTHER3]** How much does your knee bother you during this activity? No bother Slight Moderate Severe Very severe Cannot do (because of knee)
40. ✔	Comments [Comments]	**[KSSCOM]** A200
41.	Alignment *[read-only]* [Alignment]	**[ALIGNSC]** xxxxxxx.
42.	Instability *[read-only]* [Instability]	**[INSTSC]** xxxxxxx.
43.	Joint Motion *[read-only]* [Joint Motion]	**[JOINTSC]** xxxxxxx.
44.	Symptoms *[read-only]* [Symptoms]	**[SYMPSC]** xxxxxxx.
45.	Subject Satisfaction Score *[read-only]* [Subject Satisfaction Score]	**[SATSC]** xxxxxxx.
46.	Subject Expectations *[read-only]* [Subject Expectations]	**[EXPSC]** xxxxxxx.
47.	Walking and Standing *[read-only]* [Walking and Standing]	**[WLKSTSC]** xxxxxxx.
48.	Standard Activities *[read-only]* [Standard Activities]	**[STDACTSC]** xxxxxxx.
49.	Advanced Activities *[read-only]* [Advanced Activities]	**[ADVACTSC]** xxxxxxx.
50.	Discretionary Knee Activities *[read-only]* [Discretionary Knee Activities]	**[DISC]** xxxxxxx.
51.	Objective Knee Score *[read-only]* [Objective Knee Score]	**[OBJKSC]** xxxxxxx.
52.	Functional Knee Score *[read-only]* [Functional Knee Score]	**[FUNKSC]** xxxxxxx.

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TriathCone: Post-Op Events (POEVENT) [POEVENT]		
1.* ✔	Visit Date [Visit Date]	**[VSDT]** Req / Req / Req (2015-2025)
2.* ✔	Have there been any protocol defined Adverse Events since the last visit? *If Yes, complete an AE form for each event. [Protocol defined Adverse Events]	**[PROTAE]** Yes No
3.* ✔	Has the subject seen a doctor for any medical event since the last visit? [Seen doctor for medical event since last visit]	**[SEEDOC]** **[cmpSEEDOC]** Yes **[SEEDOCY]** If Yes, specify A1000 No
4.* ✔	Has the subject been hospitalized for any elective surgery since the last visit? [Subject hospitalized for elective surgery since last visit]	**[HOSP]** **[cmpHOSPY]** Yes **[ELECSURG]** Elective Surgery Contralateral knee Contralateral hip Ipsilateral hip Contralateral shoulder Ipsilateral shoulder Cataract **[cmpHOSPOT]** Other **[HOSPOT]** (Specify) A200 **[DETAILS]** Provide Details A1000 No
5.* ✔	Is anything currently affecting the subject's function? [Is anything currently affecting the subjects function]	**[AFFUNC]** **[cmpAFFUNC]** Yes **[AFUNCY]** Specify A1000

		No
6. ✔	Comments [Comments]	**[POCMT]** A200

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TriathCone: Adverse Event TriathCone (AE) - Repeating Form [AE]

#	Seq No	Onset Date	When did event occur?	Adverse Event	System Organ Class	Describe circumstances	Device Related	Meet protocol definition of seriousness	Treatment	Resolution of event	Comments	Other Treatments
1												

Adverse Event TriathCone [AE]

1. Seq No. *[read-only]*
[Seq No]

[AESEQNO]
N2

2.* Onset Date
[Onset Date]

[AESTDAT]
Req / Req / Req (2015-2025)

3.* When did event occur?
[When did event occur?]

[AEWHEN]
- Preoperative
- Perioperative (intra-operative to hospital discharge)
- Postoperative

4.* Adverse Event
[Adverse Event]

[ALLAE]
- Arthrofibrosis
- Deep Joint Infection
- Excessive Knee Pain
- Femoral Fracture
- **[cmpLOOSFC]**
  Loosening Femoral Component
  [LOOSFC]
  - Septic
  - Aseptic
- **[cmpLOOSPC]**
  Loosening Patellar Component
  [LOOSPC]
  - Septic
  - Aseptic
- **[cmpLOOSTB]**
  Loosening Tibial Component
  [LOOSTB]
  - Septic
  - Aseptic
- 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
- **[cmpWOUND]**
  Wound Related
  [AEWOUND]
  (Specify)
  A200
- **[cmpOPSITEOT]**
  Operative Site Other
  [OPSITEOT]
  (Specify)
  A200
- **[cmpAERESP]**
  Bronchopulmonary
  [AERESP]
  (Specify)
  A200
- **[cmpAECA]**
  Carcinoma
  [AECA]
  (Specify)
  A200

		[cmpAECARD] Cardiovascular [AECARD] (Specify) A200 DVT [cmpAEDERM] Dermatological [AEDERM] (Specify) A200 [cmpAEGASTRO] Gastrointestinal [AEGASTRO] (Specify) A200 [cmpAEURO] Genitourinary [AEURO] (Specify) A200 [cmpAENEURO] Neurosensory [AENEURO] (Specify) A200 Pulmonary Embolism Thrombophlebitis [cmpAETRAUMA] Trauma [AETRAUMA] (Specify) A200 [cmpOTSYS] Systemic Other [OTSYS] (Specify) A200
5.* ✔	System Organ Class [System Organ Class]	[SOC] [clSOC]
6.* ✔	Describe circumstances, including history or causative event, specify signs, symptoms and diseases [Describe circumstances]	[AECIRCUM] A1000
7.* ✔	Device Related? [Device Related]	[DVREL] [cmpDEVY]

		Yes **[DEVRELY]** If Yes or Uncertain, specify below, contact Stryker within 24 hours and send de-identified source documentation. A1000 No **[cmpDEVU]** Uncertain **[DEVRELU]** If Yes or Uncertain, specify below, contact Stryker within 24 hours and send de-identified source documentation. A1000
8.* ✔	Seriousness - Does this event meet the protocol definition of seriousness? [Meet protocol definition of seriousness]	**[AESER]** **[cmpAESER]** Yes **[AESERY]** If Yes, 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 subject death **[AESERDT]** Specify when Adverse Event became Serious. If Serious date is the same as Onset Date, enter Onset Date Req / Req / Req (2015-2025) No
9.* ✔	Treatment Contact Stryker within 24 hours if the treatment is Revision/Removal or Re-Operation For Stryker Implants, submit PER form and implant(s) to Stryker. Reoperations are for study knee only and include open manipulation/reduction. Do not include revision/removals or operations unrelated to the study knee. Other Treatments: Diagnostic tests are not considered Treatments (i.e. X-rays and MRIs should NOT be included) [Treatment]	**[AETX]** **[TXTYPE]** Yes **[REVREM]** Revisions/Removals **[FEMDT]** Femoral Component Date Req / Req / Req (2015-2025) **[FCAUGDT]** Femoral Cone Augment Date Req / Req / Req (2015-2025) **[TIBDT]** Tibial Baseplate Date Req / Req / Req (2015-2025) **[TCAUGDT]** Tibial Cone Augment Date Req / Req / Req (2015-2025) **[INSRTDT]** Tibial Insert Date Req / Req / Req (2015-2025) **[PATDT]**

		Patellar Component Date Req / Req / Req (2015-2025) **[REOPERS]** Reoperations **[cmpREOP1]** Reoperation 1 **[REOP1DT]** Date Req / Req / Req (2015-2025) **[REOP1SP]** Specify A200 **[cmpREOP2]** Reoperation 2 **[REOP2DT]** Date Req / Req / Req (2015-2025) **[REOP2SP]** Specify A200 **[cmpREOP3]** Reoperation 3 **[REOP3DT]** Date Req / Req / Req (2015-2025) **[REOP3SP]** Specify A200 Other Treatments No
10.* ✔	Resolution of event [Resolution of event]	**[RESOL]** **[cmpUNRESDT]** Unresolved **[UNRESDT]** Unresolved Status Date (Update the resolution if the Event has been resolved) Req / Req / Req (2015-2025) **[cmpRESDT]** Resolved **[RESDT]** Resolution status date Req / Req / Req (2015-2025)
11. ✔	Comments [Comments]	**[AECOMMNT]** A200

	Other Treatments	Other Treatment Date
12. ✔		

Other Treatments Entry [AE_S5]		
12.1* ✔	Other Treatments [Other Treatments]	**[OTTX]** A200
12.2* ✔	Date [Other Treatment Date]	**[OTXDT]** Req / Req / Req (2015-2025)

Key: [*] = Item is required [✔] = Source verification required [ ] = Item is collapsible [ ] = Key item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible settings are only available to users who have the rights to edit the item.

TriathCone: Study Termination (TERM) [TERM]

GENERAL INFORMATION [TERM_S1]

1.* ✔	TERMINATION DATE [TERMINATION DATE]	**[TERMDT]** Req / Req / Req (2015-2025)

STUDY TERMINATION [TERM_S2]

2.* ✔	DID SUBJECT COMPLETE STUDY ACCORDING TO PROTOCOL? Click for eHelp [Subject complete study]	**[COMPLET]** Yes No
3. ✔	CHECK ONE PRIMARY REASON Click for eHelp [Reason subject did not complete study]	**[REASON]** Screen Failure Death Investigative site terminated **[cmpLOSTFUP]** Lost to follow-up **[STLE]** List efforts to contact subject: **[STD1]** 1st phone call: Req / Req / Req (2015-2025) **[STD2]** 2nd phone call: Req / Req / Req (2015-2025) **[STD3]** 3rd phone call: Req / Req / Req (2015-2025) **[STD4]** Certified letter sent: Req / Req / Req (2015-2025) **[STAE]** Additional efforts: A1000 Revision/Removal of all implanted cone augments **[cmpNOTIMPL]** Study Device Not implanted **[STSDO]** (Specify) A1000 Subject Withdrawal **[cmpSURGNOT]** Surgery Not Performed **[STSNO]** (Specify) A1000

		[cmpOTREAS] Other **[STOTH]** (Specify) A1000
4.* ✔	WAS STUDY DEVICE IN PLACE AT DATE OF LAST CONTACT? [WAS STUDY DEVICE IN PLACE AT DATE OF LAST CONTACT]	**[DEVICE]** Yes No
COMMENTS [TERM_S3]		
5. ✔	Comments [Comments]	**[TERMCOM]** A200

Key: [✔] = Source verification required [ ] = Item is collapsible
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible settings are only available to users who have the rights to edit the item.

Appendix H

Specifications for Patient Questionnaires

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Triathlon Tritanium Cone Augments Outcomes Study

Knee Society Score: Pre-Op

GENERAL INFORMATION

Subject, please initial and date here:

SUBJECT ID: 7 6 (Study #) | ____ (Center #) | ____ (Subject #)

_____ (Initial) _____ (DD-MMM-YYYY)

SYMPTOMS

1) Pain with level walking (Please select one)

○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10

none severe

2) Pain with stairs or inclines (Please select one)

○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10

none severe

3) Does this knee feel "normal" to you? (Please select one)

○ Always ○ Sometimes ○ Never

PATIENT SATISFACTION

1) Currently, how satisfied are you with the pain level of your knee while sitting? (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

2) Currently, how satisfied are you with the pain level of your knee while lying in bed? (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

3) Currently, how satisfied are you with your knee function while getting out of bed? (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

4) Currently, how satisfied are you with your knee function while performing light household duties? (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

5) Currently, how satisfied are you with your knee function while performing leisure recreational activities? (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

Knee Society Score: Pre-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | | (Center #) | | | | | (Subject #)

PATIENT EXPECTATION

What do you expect to accomplish with your knee replacement:

1) **Do you expect your knee joint replacement surgery will relieve your knee pain?** (Please select one)
   - ◯ No, not at all
   - ◯ Yes, a little bit
   - ◯ Yes, somewhat
   - ◯ Yes, a moderate amount
   - ◯ Yes, a lot

2) **Do you expect your surgery will help you carry out your normal activites of daily living?** (Please select one)
   - ◯ No, not at all
   - ◯ Yes, a little bit
   - ◯ Yes, somewhat
   - ◯ Yes, a moderate amount
   - ◯ Yes, a lot

3) **Do you expect your surgery will help you perform leisure, recreational or sports activities?** (Please select one)
   - ◯ No, not at all
   - ◯ Yes, a little bit
   - ◯ Yes, somewhat
   - ◯ Yes, a moderate amount
   - ◯ Yes, a lot

Knee Society Score: Pre-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | (Center #) | | | | | (Subject #)

FUNCTIONAL ACTIVITIES

WALKING AND STANDING

1) **Can you walk without any aids (such as a cane, crutches or wheelchair)?** (Please select one)
   - ◯ Yes
   - ◯ No

2) **If no, which of the following aids(s) do you use?** (Please select one)
   - ◯ Wheelchair
   - ◯ Walker
   - ◯ Crutches
   - ◯ Two canes
   - ◯ One crutch
   - ◯ One cane
   - ◯ Knee sleeve / brace
   - ◯ Other (Specify) _____

3) **Do you use these aid(s) because of your knees?** (Please select one)
   - ◯ Yes
   - ◯ No

4) **For how long can you stand (with or without aid) before sitting due to knee discomfort?** (Please select one)
   - ◯ Cannot stand
   - ◯ 0 - 5 minutes
   - ◯ 6 - 15 minutes
   - ◯ 16 - 30 minutes
   - ◯ 31 - 60 minutes
   - ◯ More than an hour

5) **For how long can you walk (with or without aid) before stopping due to knee discomfort?** (Please select one)
   - ◯ Cannot walk
   - ◯ 0 - 5 minutes
   - ◯ 6 - 15 minutes
   - ◯ 16 - 30 minutes
   - ◯ 31 - 60 minutes
   - ◯ More than an hour

Knee Society Score: Pre-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) ☐☐ (Center #) ☐☐☐☐ (Subject #)

FUNCTIONAL ACTIVITIES *continued...*

STANDARD ACTIVITIES

How much does your knee bother you during each of the following activities? (Please select one per row)

1) Walking on an uneven surface

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

2) Turning or pivoting on your leg

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

3) Climbing up or down a flight of stairs

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

4) Getting up from a low couch or a chair without arms

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

5) Getting into or out of a car

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

6) Moving laterally (stepping to the side)

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

ADVANCED ACTIVITIES

1) Climbing a ladder or step stool

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

2) Carrying a shopping bag for a block

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

3) Squatting

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

4) Kneeling

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

5) Running

◯ No bother ◯ Slight ◯ Moderate ◯ Severe ◯ Very severe ◯ Cannot do (because of knee) ◯ I never do this

Knee Society Score: Pre-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | | (Center #) | | | | | (Subject #)

FUNCTIONAL ACTIVITIES *continued..*

DISCRETIONARY KNEE ACTIVITIES

Please check 3 of the activities below that you consider *most important* to you.
(Please do not write in additional activities)

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (> 30 mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)
- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity
(Please write the 3 activities from list above)

1) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

2) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

3) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

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Triathlon Tritanium Cone Augments Outcomes Study

Lower Extremity Activity Scale

Subject, please initial and date here:

_____ (Initial)

_____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | (Center #) | | | | | (Subject #)

VISIT INTERVAL:

○ Pre op ○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

Please read through each description given below, pick the ONE description that best describes your regular daily activity and put a check in that circle (Check only one circle).

1. ○ I am confined to bed all day.
2. ○ I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc.).
3. ○ I am either in bed or sitting in a chair most of the day.
4. ○ I sit most of the day, except for minimal transfer activities, no walking or standing.
5. ○ 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.)
6. ○ 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.
7. ○ I walk around my house and go outside at will, walking one or two blocks at a time.
8. ○ I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting).
9. ○ 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).

10a. ○ I am up and about at will in my house and outside. I also work outside the house in a minimally active job.

10b. ○ I am up and about at will in my house and outside. I also work outside the house in a moderately active job.

10c. ○ I am up and about at will in my house and outside. I also work outside the house in a extremely active job.

11a. ○ I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming occasionally (2-3 times per month).

11b. ○ I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming occasionally 2-3 times per week.

11c. ○ I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming daily.

12a. ○ I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports occasionally (2-3 times per month).

12b. ○ I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports occasionally 2-3 times per week.

12c. ○ I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports daily.

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Triathlon Tritanium Cone Augments Outcomes Study

SF-12v2™ Health Survey

Subject, please initial and date here:

_____ (Initial) _____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | ____ (Center #) | ____ (Subject #)

VISIT INTERVAL:

○ Pre op ○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

I. SF-12v2 Health Survey Standard Version

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark the circle that best describes your answer.

1) In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
○	○	○	○	○

2) The following questions are about activities you might do during a typical day. Does <u>your health now limit</u> you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. **<u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**	○	○	○
b. **Climbing <u>several</u> flights of stairs**	○	○	○

3) During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

a. **<u>Accomplished less</u> than you would like**

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

b. **Were limited in the <u>kind</u> of work or other activities**

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

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

a. **<u>Accomplished less</u> than you would like**

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

b. **Did work or activities <u>less carefully than usual</u>**

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

stryker® Triathlon Tritanium Cone Augments Outcomes Study

SF-12v2™ Health Survey

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | ☐☐ (Center #) | ☐☐☐☐ (Subject #)

VISIT INTERVAL:

○ Pre op ○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

I. SF-12v2 Health Survey Standard Version (CONTINUED)

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

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

---

6) 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...

a. **Have you felt calm and peaceful?**

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

b. **Did you have a lot of energy?**

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

c. **Have you felt downhearted and depressed?**

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

---

7) 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.)?

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 Tritanium Cone Augments Outcomes Study

End - of - Stem Pain Diagram

Subject, please initial and date here:

_____ (Initial)

_____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | ___ (Center #) | ____ (Subject #)

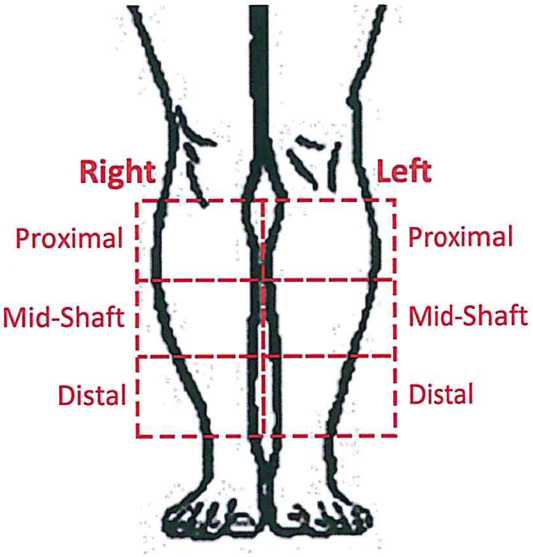
VISIT INTERVAL: ○ Pre op ○ 6 Wk ○ 2 Yr ○ 5 Yr

OPERATIVE SIDE: ○ Left ○ Right

1. Please indicate if you are experiencing **shin pain**.
   Please select a level of pain and draw an **X** within the **red box** to indicate the location.

   ○ No Pain
   ○ Pain with Extreme Activity Only
   ○ Pain with Moderate Activity
   ○ Pain with Normal Activity
   ○ Pain at Rest

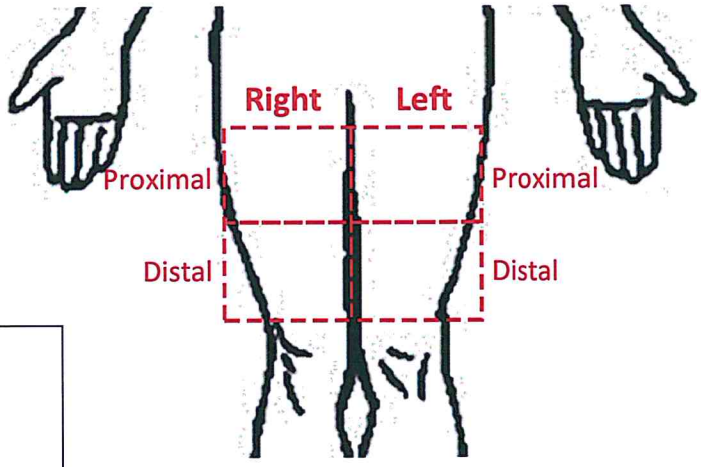
   Additional Comments:



2. Please indicate if you are experiencing **thigh pain**.
   Please select a level of pain and draw an **X** within the **red box** to indicate the location.

   ○ No Pain
   ○ Pain with Extreme Activity Only
   ○ Pain with Moderate Activity
   ○ Pain with Normal Activity
   ○ Pain at Rest

   Additional Comments:



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Triathlon Tritanium Cone Augments Outcomes Study

EQ-5D Health Questionnaire

Subject, please initial and date here:

_____ (Initial)

_____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | _ _ (Center #) | _ _ _ _ (Subject #)

VISIT INTERVAL:

○ Pre op ○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- ○ I have no problems in walking about
- ○ I have some problems in walking about
- ○ I am confined to bed

Self-Care

- ○ I have no problems with self-care
- ○ I have some problems washing or dressing myself
- ○ I am unable to wash or dress myself

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

- ○ I have no problems with performing my usual activities
- ○ I have some problems with performing my usual activities
- ○ I am unable to perform my usual activities

Pain / Discomfort

- ○ I have no pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have extreme pain or discomfort

Anxiety / Depression

- ○ I am not anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am extremely anxious or depressed

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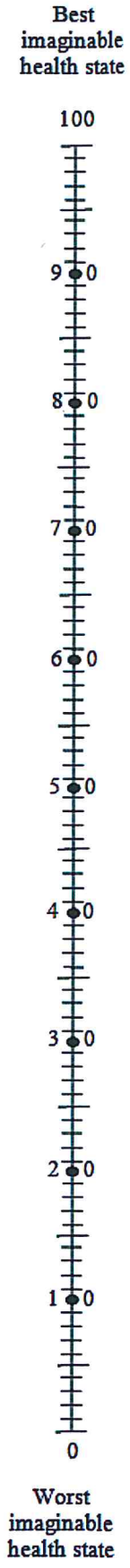
EQ-5D Health Questionnaire

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



SUBJECT ID: 7 6 (Study #) | (Center #) | (Subject #)

VISIT INTERVAL:

○ Pre op	○ 6 Wk	○ 6 Mo	○ 1 Yr	○ 2 Yr	○ 5 Yr

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Triathlon Tritanium Cone Augments Outcomes Study

HSS Patella Score

Subject, please initial and date here:

_____ (Initial)

_____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | _ _ (Center #) | _ _ _ _ (Subject #)

VISIT INTERVAL:

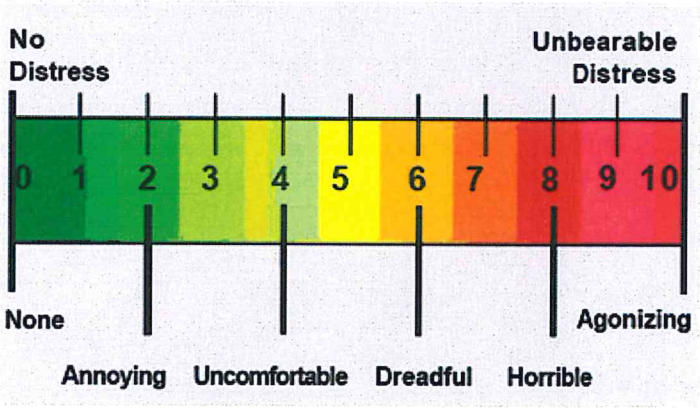
○ Pre op ○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

INSTRUCTIONS:

This survey asks for your view about your knee pain. This information will keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

A. Using the scale on the right, rate the pain you experience on the front of your knee while rising from a low chair:

☐ (0-10)



B. Do you feel that the anterior (front) part of your knee is limiting you while:

1. Climbing stairs? ○ Yes ○ No

2. Descending stairs? ○ Yes ○ No

3. Sitting for prolonged time (30 minutes at 90°)? ○ Yes ○ No

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Triathlon Tritanium Cone Augments Outcomes Study

Knee Society Score: Post-Op

Subject, please initial and date here:

_____ (Initial) _____ (DD-MMM-YYYY)

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | _ _ (Center #) | _ _ _ _ (Subject #)

VISIT INTERVAL:

○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

1) **Height:** _____ cm / in ☐ Decline to answer 2) **Weight:** _____ lbs / kg ☐ Decline to answer

SYMPTOMS

1) **Pain with level walking** (Please select one)

○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10

none severe

2) **Pain with stairs or inclines** (Please select one)

○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10

none severe

3) **Does this knee feel "normal" to you?** (Please select one)

○ Always ○ Sometimes ○ Never

PATIENT SATISFACTION

1) **Currently, how satisfied are you with the pain level of your knee while sitting?** (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

2) **Currently, how satisfied are you with the pain level of your knee while lying in bed?** (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

3) **Currently, how satisfied are you with your knee function while getting out of bed?** (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

4) **Currently, how satisfied are you with your knee function while performing light household duties?** (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

5) **Currently, how satisfied are you with your knee function while performing leisure recreational activities?** (Please select one)

○ Very Satisfied ○ Satisfied ○ Neutral ○ Dissatisfied ○ Very Dissatisfied

Knee Society Score: Post-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | ___ (Center #) | ____ (Subject #)

VISIT INTERVAL:

○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

PATIENT EXPECTATION

Compared to what you expected before your knee replacement:

1) **My expectations for pain relief were...** (Please select one)
   - ○ Too High - "I'm a lot worse than I thought"
   - ○ Too High - "I'm somewhat worse than I thought"
   - ○ Just Right - "My expectations were met"
   - ○ Too Low - "I'm somewhat better than I thought"
   - ○ Too Low - "I'm a lot better than I thought"

2) **My expectations for being able to do my normal activities of daily living were...** (Please select one)
   - ○ Too High - "I'm a lot worse than I thought"
   - ○ Too High - "I'm somewhat worse than I thought"
   - ○ Just Right - "My expectations were met"
   - ○ Too Low - "I'm somewhat better than I thought"
   - ○ Too Low - "I'm a lot better than I thought"

3) **My expectations for being able to do my leisure, recreational or sports activities were...** (Please select one)
   - ○ Too High - "I'm a lot worse than I thought"
   - ○ Too High - "I'm somewhat worse than I thought"
   - ○ Just Right - "My expectations were met"
   - ○ Too Low - "I'm somewhat better than I thought"
   - ○ Too Low - "I'm a lot better than I thought"

Knee Society Score: Post-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | (Center #) | | | | | (Subject #)

VISIT INTERVAL:

○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

FUNCTIONAL ACTIVITIES

WALKING AND STANDING

1) **Can you walk without any aids (such as a cane, crutches or wheelchair)?** (Please select one)
   - ○ Yes
   - ○ No

2) **If no, which of the following aids(s) do you use?** (Please select one)
   - ○ Wheelchair
   - ○ Walker
   - ○ Crutches
   - ○ Two canes
   - ○ One crutch
   - ○ One cane
   - ○ Knee sleeve / brace
   - ○ Other (Specify) _____

3) **Do you use these aid(s) because of your knees?** (Please select one)
   - ○ Yes
   - ○ No

4) **For how long can you stand (with or without aid) before sitting due to knee discomfort?** (Please select one)
   - ○ Cannot stand
   - ○ 0 - 5 minutes
   - ○ 6 - 15 minutes
   - ○ 16 - 30 minutes
   - ○ 31 - 60 minutes
   - ○ More than an hour

5) **For how long can you walk (with or without aid) before stopping due to knee discomfort?** (Please select one)
   - ○ Cannot walk
   - ○ 0 - 5 minutes
   - ○ 6 - 15 minutes
   - ○ 16 - 30 minutes
   - ○ 31 - 60 minutes
   - ○ More than an hour

Knee Society Score: Post-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) ☐☐ (Center #) ☐☐☐☐ (Subject #)

VISIT INTERVAL:

○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

FUNCTIONAL ACTIVITIES *continued...*

STANDARD ACTIVITIES

How much does your knee bother you during each of the following activities? (Please select one per row)

1) **Walking on an uneven surface**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

2) **Turning or pivoting on your leg**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

3) **Climbing up or down a flight of stairs**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

4) **Getting up from a low couch or a chair without arms**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

5) **Getting into or out of a car**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

6) **Moving laterally (stepping to the side)**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

ADVANCED ACTIVITIES

1) **Climbing a ladder or step stool**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

2) **Carrying a shopping bag for a block**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

3) **Squatting**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

4) **Kneeling**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

5) **Running**
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee) ○ I never do this

Knee Society Score: Post-Op

GENERAL INFORMATION

SUBJECT ID: 7 6 (Study #) | | | (Center #) | | | | (Subject #)

VISIT INTERVAL:

○ 6 Wk ○ 6 Mo ○ 1 Yr ○ 2 Yr ○ 5 Yr

FUNCTIONAL ACTIVITIES *continued...*

DISCRETIONARY KNEE ACTIVITIES

Please check 3 of the activities below that you consider *most important* to you.
(Please do not write in additional activities)

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (> 30 mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)
- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity
(Please write the 3 activities from list above)

1) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

2) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

3) _____
○ No bother ○ Slight ○ Moderate ○ Severe ○ Very severe ○ Cannot do (because of knee)

Triathlon Cone Augments Outcomes Study 1

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~~TKA 1.0 Outcomes Study~~
FOLLOW-UP QUESTIONNAIRE

Subject, please initial and date here:

_____ (Initial) _____ (DD-MMM-YYYY)

_____ (Coordinator Initial) _____ (DD-MMM-YYYY)

General Information

Subject ID: 7 9 | Study # 76 | Center # | Subject #

Visit Interval:

O O O O O

~~3 yr~~ ~~4 yr~~ ~~5 yr~~ ~~8 yr~~ ~~9 yr~~

6 yr 7 yr 9 yr 9 yr 10 yr

1. **Questionnaire completed by: (*Please choose one*)**
   - O Office Visit
   - O Mail
   - O Phone
   - O E-mail

2. **Do you have any pain in your knee that has the study knee replacements? (*Please choose one*).**
   - O Yes (specify)
   - O ~~No (specify)~~

3. **Are you satisfied with the results of your study knee replacement? (*Please choose one*).**
   - O Yes
   - O No (specify)

4. **Have you had any surgery on your study knee since your last study required visit/contact? (*Please choose one*).** If you are unsure, please contact your study coordinator.
   - O Yes
     - Cone augment
     - o Is your tibial baseplate of your study knee still implanted?
       - o Yes
       - o No
       - Didn't Receive (For study coordinator only)
     - o Is your femoral component of your study knee still implanted?
       - o Yes Cone augment
       - o No
   - O ~~No (specify)~~ Didn't Receive (For study coordinator only)

Dynamic

Coordinator comment (for staff use only):

Appendix I

Product Labeling

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143393

Device Name
Triathlon® Tritanium® Cone Augments

Indications for Use *(Describe)*

General Total Knee Arthroplasty (TKR) Indications:

• Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
• Post-traumatic loss of knee joint configuration and function.
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Revision of previous unsuccessful knee replacement or other procedure.
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:
• Severe instability of the knee secondary to compromised collateral ligament integrity or function.
Indications for Bone Augments:
• Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
• Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:
• Severe degeneration or trauma requiring extensive resection and replacement
• Femoral and Tibial bone voids
• Metaphyseal reconstruction

The Triathlon TS Cone Augment components are intended for cemented or cementless use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190991

Device Name
Triathlon Total Knee System

Indications for Use *(Describe)*

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:

- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon Tritanium® Cone Augment components are intended for cemented or cementless use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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