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Orthopaedics

Triathlon Tritanium Knee Outcomes Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center study of the outcomes of the Triathlon Tritanium Knee System

Sponsor:	*Stryker Orthopaedics* *325 Corporate Drive* *Mahwah, NJ 07430* *201-831-5000*
Study Product:	*Triathlon Tritanium Tibia and Patella*
Protocol Number:	*74*
510(k) Clearance Number:	*K123486 & K132624*

Version 2

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CONFIDENTIAL

Protocol Change History

Version	Description	Changed By
1	New	Michael A. Pelosi
2	Added cemented treatment group Updated evaluation schedule (removed FJS-12, LEAS and EQ5D) Added evaluation schedule for cemented treatment group Updated statistical section & sample size Updated draft specs for CRFs Updated component listing Updated 6 month visit interval window	Michael A. Pelosi

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List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
AP	Anteroposterior
BMI	Body Mass Index
CFR	Code of Federal Regulations
CP	Commercially Pure
CR	Cruciate Retaining
CSM	Clinical Study Manager
DCR	Data Clarification Request
EC	Ethics Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
GCP	International Conference of Harmonisation Good Clinical Practice
HHS	Harris Hip Score
HIPAA	Health Insurance Portability and Accountability Act
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
KSS	Knee Society Score, 2011
LRM	Laser Rapid Manufacturing
ML	Mediolateral
OKS	Oxford Knee Score
PA	Periapatite
PCL	Posterior Cruciate Ligament
PER	Product Experience Report
PI	Principal Investigator
PMMA	Polymethylacrylate
PRO	Patient Reported Outcome
PS	Posterior Stabilized
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 study of the outcomes of the Triathlon Tritanium Knee System
Short Title	Triathlon Tritanium Knee Outcomes Study
Protocol Number	74
Phase	Post-market
Methodology	This study is a prospective, non-randomized evaluation of the Triathlon Tritanium Knee System for primary total knee arthroplasty (TKA) with a cementless application in a consecutive series of patients who meet the eligibility criteria. Cohort 1 (cementless): The first 356 cases enrolled will receive the Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella, Triathlon CR or PS Beaded Femur with PA and the Triathlon Tibial Insert. All components in this cohort must be used in a cementless application. Cohort 2 (cemented): An additional 144 cases will receive the Triathlon Cemented Tibial Baseplate, Triathlon Cemented Patella, Triathlon CR or PS Cemented Femur and Triathlon Tibial Insert. All components in this cohort must be used in a cemented application. The study uses literature control for the primary endpoint and a concurrent control (Cohort 2) for secondary endpoints.
Study Duration	Approximate 12-year total duration • Enrollment period of 24 months • Follow-up of each primary Cohort 1 (cementless)TKA case to 10 years • Follow-up of each primary Cohort 2 (cemented) TKA case to 5 years.
Study Center(s)	5-10 centers. The same center may be included in both arms. Conversely, a center may choose to participate in only a single arm.

Hypothesis	The success rate of the Triathlon Tritanium Knee, defined as absence of revision for aseptic loosening of the tibial baseplate at 2 years, is no worse than rates reported in the literature for cemented devices.
Objective(s)	Primary: To compare the rate of aseptic loosening of the Triathlon Tritanium Tibial Baseplate with rates reported in the literature for cemented tibial baseplates at 2 years postoperative. Secondary Objectives: To assess the Kaplan-Meier survival curves of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella and compare them with those reported for cemented knee components in the literature. The overall revision rate will evaluate all-cause revision and removal rates of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella. To compare functional scores and Patient Reported Outcomes (PROs) between Cohort 1 (cementless) and Cohort 2 (cemented) at 2 years postoperative. The following outcomes measures will be collected: • 2011 Knee Society Score (2011 KSS) • Oxford Knee Score (OKS) • Short Form-12 (SF-12)

Additional Data Collection	• Subject demographics and medical histories are collected (age, gender, primary diagnosis, BMI, comorbidities, medications used, smoking history, alcohol use, education level, employment status, confounding orthopedic problems, etc.). • 2011 KSS, OKS and SF-12 will be presented with respect to improvement from preoperative scores for the cohorts according to their respective evaluation schedules. • Assessment of radiographic outcomes using Anteroposterior (AP), Mediolateral (ML) and Merchant radiographs for the cohorts according to their respective evaluation schedules. . • A Follow-up Questionnaire is administered to assess patient satisfaction, pain, study device survivorship and capture adverse events (AEs) for the cohorts according to their respective evaluation schedules. • Collection and evaluation of device related AEs and unanticipated adverse device effects (UADEs).
Number of Subjects	A total of 500 cases will be enrolled in the study. Cohort 1 (cementless): 356 cementless cases Cohort 2 (cemented): 144 cemented cases • Cases must receive the appropriate study device to count toward enrollment.

Diagnosis and Main Inclusion/Exclusion Criteria	Inclusions: 1. Patient has signed an IRB/EC approved; study specific Informed Patient Consent Form. 2. Patient is a male or non-pregnant female age 18-75 years at time of study device implantation. 3. Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD). 4. Patient is a candidate for primary cementless total knee replacement, including a resurfaced patella. 5. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation. Exclusions: 1. Patient has a Body Mass Index (BMI) > 40. 2. Patient has a diagnosis of avascular necrosis or inflammatory arthritis. 3. Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation. 4. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device. 5. Subject is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's Disease) leading to progressive bone deterioration. 6. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days). 7. Patient is diagnosed with lumbar radicular pain. 8. Patient has a known sensitivity to device materials. 9. Patient is a prisoner.

Study Device Cohort 1 (cementless)	Required Components for the cementless cohort: • Triathlon Tritanium Tibial Baseplate • Triathlon Tritanium Patella All components must be used in a cementless application.
Ancillary Devices Cohort 1 (cementless)	All Stryker components must be used according to this study protocol. The following ancillary devices are permissible: • Triathlon Cruciate Retaining (CR) or Posterior Stabilized (PS) Beaded Femur with Periapatite (PA) • Triathlon Tibial Inserts All components must be used in a cementless application.
Control Device Cohort 2 (cemented)	Required Components for the cemented cohort: • Triathlon Tibial Baseplate • Triathlon Patella • Triathlon CR or PS Femoral Component • Triathlon Tibial Inserts All components must be used in a cemented application.
Reference Therapy	Literature control (cemented tibial baseplates) Concurrent control (Triathlon Cemented)

Statistical Methodology	**Primary Objective:** • 2-year success rate of the Triathlon Tritanium Tibial Baseplate with an endpoint of revision for aseptic loosening will be compared to a 99% success rate with a 2% noninferiority margin. **Secondary Objectives:** • The Kaplan-Meier survival curves for all-cause revision/removal of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella will be displayed. • The all-cause revision/removal rates of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella will be compared with those reported for cemented knee components in the literature. • The 2011 KSS scores, SF-12, and OKS scores at 2 years postoperative will be compared between Cohort1 (cementless) and Cohort 2 (cemented) using applicable statistical methods.

Cohort 1 (Cementless) Evaluation Schedule

Evaluation	Preop X-rays (-1 yr) CRFs (-4 mos)	Intraop	6 wks (± 3 wks)	6 mo (-14 - + 4 wks)	1 yr (± 2 mos)	2 yrs (± 2 mos)	3 yrs (± 3 mos)	4 yrs (± 4 mos)	5 yrs (± 4 mos)	Annually 6, 7, 8, 9 yrs (± 4 mos)	10 yrs (± 4 mos)
Inclusion/Exclusion	X										
Demographics & Medical History	X										
Surgical Details		X									
Preoperative Functional Evaluation	X										
Postoperitive Functional Evaluation			X	X	X	X			X		X
OKS	X		X		X	X	X	X	X	X	X
SF-12	X		X		X	X	X	X	X	X	X
Radiographs: AP/ML/Merchant	X		X	X	X	X			X		X
Follow-up Questionnaire							X	X	X	X	X

X: Evaluation is required for all cases.

Functional Evaluation - The Functional Evaluations include the 2011 KSS, a standardized instrument with both patient reported outcomes and surgeon completed sections that evaluate function, satisfaction, expectations and range of motion.
OKS - The Oxford Knee Score is a 12 item patient reported outcome questionnaire that evaluates function and pain after total knee arthroplasty.
SF-12 - The SF-12 is a standardized 12 item patient reported outcome questionnaire that evaluates general health and well being.
Follow-up Questionnaire - The Follow-up Questionnaire is a short patient questionnaire intended to provide information on patient satisfaction, pain, study device survivorship and AEs.

Cohort 2 (Cemented) Evaluation Schedule

Evaluation	Preop X-rays (-1 yr) CRFs (-4 mos)	Intraop	6 wks (± 3 wks)	6 mo (-14 - + 4 wks)	1 yr (± 2 mos)	2 yrs (± 2 mos)	3 yrs (± 3 mos)	4 yrs (± 4 mos)	5 yrs (± 4 mos)
Inclusion/Exclusion	X								
Demographics & Medical History	X								
Surgical Details		X							
Preoperative Functional Evaluation	X								
Postoperitive Functional Evaluation			X	X	X	X			X
OKS	X		X		X	X	X	X	X
SF-12	X		X		X	X	X	X	X
Radiographs: AP/ML/Merchant	X		X	X	X	X			X
Follow-up Questionnaire							X	X	X

X: Evaluation is required for all cases.

Functional Evaluation - The Functional Evaluations include the 2011 KSS, a standardized instrument with both patient reported outcomes and surgeon completed sections that evaluate function, satisfaction, expectations and range of motion.
OKS - The Oxford Knee Score is a 12 item patient reported outcome questionnaire that evaluates function and pain after total knee arthroplasty.
SF-12 - The SF-12 is a standardized 12 item patient reported outcome questionnaire that evaluates general health and well being.
Follow-up Questionnaire - The Follow-up Questionnaire is a short patient questionnaire intended to provide information on patient satisfaction, pain, study device survivorship and AEs.

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

Primary TKA has consistently shown to be successful in relieving pain and improving function for those experiencing difficulties of degenerative joint disease[1].

The Triathlon Knee System, a predecessor to the Triathlon Tritanium Knee System, is designed to meet patients' reasonable expectations for lifestyle recovery. It is designed to provide patients with more natural motion and the potential for greater implant longevity. As a next-generation knee replacement, the Triathlon Knee System is designed to more closely mimic natural knee motion, providing mobility with stability through or exceeding 150° of flexion[2]. The Triathlon design criteria are realized through component features including an anatomic radius, deep flexion radius and flared posterior condyles, a patented Rotary Arc and an anatomic patellofemoral track.

Studies of kinematics and biomechanics have identified a constant radius in natural knee motion centered about the transepicondylar axis[3,4,5]. The Triathlon Knee System is the first of its kind with a patented anatomic radius. Centering the anatomic radius about the transepicondylar axis provides ligament isometry, not only in full extension and 90° of flexion, but through the entire range of motion. The anatomic radius is designed to mimic natural knee motion, enhancing stability and mobility in activities such as descending and ascending stairs or any similar activity requiring stability at deep flexion angles.

Cementless fixation in TKA was initially introduced in the early 1980s[6]. As materials and designs have evolved, cementless fixation has become a growing trend in knee reconstruction, mainly due to the changing demographics of the TKA population[7]. Cementless components offer the potential advantage of a biologic interface between the bone and implants, which could demonstrate the greatest advantage in long-term durable fixation in the follow-up of younger patients undergoing TKA[7].

The Triathlon Tritanium Knee System features the Tritanium advanced fixation technology. Tritanium technology provides a three-dimensional, commercially pure (CP) Titanium matrix that resembles trabecular bone, allowing for enhanced fixation[8] and joint stability. Studies have shown the superiority of 3-D surfaces when compared to 2-D surfaces, as well as improved biological fixation with CP Titanium as compared to alloys[9].

Tritanium porous surface technology allows the component to be press fit into the prepared tibia. The key feature of this Tritanium technology porous coating is that it has a higher pore volume than other standard porous coatings, which may allow greater biologic fixation when press fit. An animal study on a similar porous tantalum coating with a volume porosity of 75-80% showed superior mechanical and biologic fixation properties when compared to a coating with other surface treatments[10].

The Triathlon Tritanium Knee System incorporates the Tritanium porous biologic fixation technology with the Triathlon Knee System design, which provides orthopaedic surgeons with enhanced biologic fixation technology for primary cementless TKA indications to intraoperatively address initial and long-term fixation.

1.2 Study Device

The Triathlon Tritanium Tibial Baseplate was cleared for use under FDA 510(k) K123486 on May 3, 2013. The Triathlon Tritanium Patella was cleared for use under FDA 510(k) K132624 on November 26, 2013. See Appendix A for the FDA 510(k) clearance letters.

The Triathlon Tritanium Tibial Baseplate is indicated for cemented and uncemented use but must be used in a cementless, press-fit application for the purposes of this study protocol. It is available in eight sizes and is manufactured from Ti-6Al-4V-ELI (ASTM F-136) and CP Titanium powder (ASTM F-1580) materials. The bone contacting material on the fixation side of the baseplate is manufactured from CP Titanium, providing a porous surface. The porous material is located on the underside of the tray and also on the proximal portion of the pegs and keel.

The Triathlon Tritanium Patella is indicated for cemented or cementless use but must be used in a cementless, press-fit application for the purposes of this study protocol. The patella is offered in asymmetric and symmetric designs. The asymmetric design is available in five

superior/inferior dimensions and three dome thicknesses. The symmetric design is offered in four diameters and the same three thicknesses. It is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE, ASTM F648) and commercially pure titanium powder (CPTi, ASTM F1580).

All study devices need to be used in a cementless, press-fit application for the purposes of this protocol.

Details of the device design are presented in Section 6, Device Description.

1.3 Preclinical Data

The following bench tests (with test report numbers) were conducted with the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella:

Static Shear Test (RD-12-042)
The mean moment for the Triathlon Tritanium Baseplate under load was 31.68 N-m.

Evaluation of the Triathlon Tritanium Baseplate Locking Mechanism (RD-12-110)
The locking tabs remained intact after 220,000 cycles as determined by visual and tactile inspection.

Characterization of Tritanium Primary Baseplates under Impaction Loads (RD-12-055)
The Tritanium Tibial Baseplate generated < 1mg of CP Titanium debris under 10 microns in size.

Dynamic Shear Evaluation of the Triathlon Tritanium Tibial Peg (RD-12-056)
The four pegs of the Tritanium Tibial Baseplate resisted the shear forces incurred by a dynamic load simulating stair descent activity for 1 million cycles or 10 years of simulated implant life.

Triathlon Tritanium Baseplate Cantilever Fatigue Test (RD-12-111)
All samples showed no fractures at the superior side of the Posterior Cruciate Ligament (PCL) or the outer strut on the inferior side of the tray at 10 million cycles of testing.

Triathlon Tritanium Baseplate Cantilever Fatigue Test after Impaction (RD-12-112)

All samples showed no fractures at the superior side of the PCL or the outer strut on the inferior side of the tray at 10 million cycles and the baseplate was able to carry load throughout the entire test.

Triathlon Tritanium Baseplate Anterior-Posterior Fatigue Test (RD-12-113)

All samples completed the required 10 million cycles with no visual evidence of fracture.

Wear Evaluation using Triathlon Tritanium Baseplates (RD-12-088)

The study showed no difference in the backside wear rates of polyethylene inserts mated with standard Triathlon Cobalt Chromium baseplates compared to those mated with Triathlon Tritanium baseplates.

Cement and Tritanium Shear Bond Strength Test (RD-12-118)

The median fatigue strength of the cement/Tritanium (Patella) interface was calculated to be 2251N. The median fatigue strength of the cement/Tritanium (Baseplate) interface was calculated to be 3922N.

Evaluation of the Triathlon Tritanium Patella under Adverse Loading Conditions (RD-12-097)

There were no signs of polyethylene fracture, dissociation of the polyethylene from the metal backing, or shear of the metal pegs after 1 million cycles of simulated adverse stair climbing kinematics and loading parameters at 10° of lateral tilt.

Tritanium Patella Static Tensile Bond Strength of Poly/Metal Interface (RD-12-044)

The mean peak load for the Triathlon Tritanium Patella for the tensile bond strength test was 2428 N.

Triathlon Tritanium Patella Static Shear Test (RD-12-115)

The mean peak load for the Triathlon Tritanium Patella static shear test was 16,157 N.

The results of the bench top testing conducted for the Triathlon Tritanium Tibial Baseplate and Patella identified acceptance criteria were met.

Copies of all test reports are available at Stryker Orthopaedics.

1.4 Clinical Data to Date

This study is the first Stryker sponsored multi-center prospective data collection on the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella.

The following articles are available from Stryker sponsored multi-center prospective studies on control device, the Triathlon cemented knee system:

1. Harwin SF, Greene KA, Hitt K. Triathlon total knee arthroplasty: 4-year outcomes with a high-performance implant. J Knee Surg. 2008 Oct;21(4):320-6.

2. Roth JS, Buehler KC, Shen J, Naughton M. Patient factors predict functional outcomes after cruciate retaining TKA: A 2-year follow-up analysis Journal of Arthroplasty, 2013 Mar 21[Epub ahead of print].

3. Harwin SF, Greene KA, Hitt K. Early experience with a new total knee implant: maximizing range of motion and function with gender-specific sizing. Surg Technol Int. 2007;16:199-205.

4. Lozano S, Shen J, Doumato D: Functional Outcome in High Activity Demand Patients Following Total Knee Arthroplasty. Orthopedics. 2012 May; 35(5): e681-90.

5. Lozano S, Shen J, Doumato D: Cruciate Retaining vs. Posterior Stabilized Inserts in Total Knee Arthroplasty: Functional Outcomes Comparison. Journal of Arthroplasty. 2012 July 16. [Epub ahead of print].

2 Study Objectives

2.1 Efficacy

2.1.1 Primary

The primary objective of this study is to evaluate the success rate of cementless primary total knee replacement with the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella. Success will be defined as absence of tibial baseplate revision for aseptic loosening at 2 years postoperative. It is expected that the success rate of the Triathlon Tritanium Tibial Baseplate will be non-inferior to the selected reference rate of 99% at 2 years postoperative.

2.1.2 Secondary

The secondary objectives of this study are:

- To assess the Kaplan-Meier survival curves of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella and compare them with those reported for cemented knee components in the literature. The overall revision rate will evaluate all-cause revision and removal rates of the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella.
- To compare 2011 KSS scores, SF-12 scores, and OKS scores between Cohort 1 (cementless) and Cohort 2 (cemented) at 2 years postoperative.

2.1.3 Additional Data Collection

Patient Demographics and Medical History:

Preoperative clinical data are collected and include, but may not be limited to: age, gender, operative side, primary diagnosis, height, weight, BMI, comorbidities, medications used, smoking history, alcohol use, education level, employment status and confounding orthopedic problems for both cohorts.

Clinical Outcomes:

Clinical outcomes are evaluated for both cohorts according to their respective evaluation schedules with the 2011 KSS. The 2011 KSS is comprised of five components (Demographics, Objective Knee Score, Patient Expectation, Patient Satisfaction Score and Functional Knee Score) that are physician and patient derived.[11], The score includes elements of pain, motion and function.

Patient Reported Outcomes:

Pain, function and health related QOL will be evaluated for both cohorts according to their respective evaluation schedules with the SF-12, OKS and patient derived 2011 KSS components. The SF-12 is a 12 item patient self-assessment evaluating health and general well being. The OKS is a 12 item patient reported outcome questionnaire that evaluates function and pain after total knee arthroplasty. The 2011 KSS subjective component is a patient reported outcome measure based on satisfaction with outcome, fulfillment of expectations and ability to perform functional activities.[12]

A Follow-up Questionnaire is administered annually for both cohorts according to their respective evaluation schedules to assess for patient satisfaction, pain, study device survivorship and to capture AEs. This questionnaire provides the information necessary to create an accurate Kaplan-Meier Survival Curve.

Radiographic Outcomes:

Radiographs are taken and collected in the AP, ML and Merchant views for both cohorts according to their respective evaluation schedules (see Appendix B for the radiographic technique to be used). Radiographs are evaluated by an independent reviewer. Parameters for radiographic failures will follow the guidelines that have been set by the Knee Society[13]. The scoring system for each of the three components is determined by measuring the width of the radiolucent lines for each of the zones in millimeters for each of the three components. The total widths are added for each zone for each of the three prostheses. The total produces a numerical score for each component. Failure is defined as a score of 10 or greater, regardless of symptoms. A migrating or shifting prosthesis, with or without the disappearance of radiolucent lines, should be considered as a possible or impending failure regardless of the score. Evaluation of the radiographs includes, but is not limited to, radiolucency and subsidence of the tibial baseplate, patellar component positioning, patellar tilt and/or displacement and osteolysis.

Radiographic Performance Requirements:

Radiographic analysis of the tibial component employs 3 zones (Zone 1 – Zone 3) in the ML view and five zones (Zone 1 – Zone 5) in the AP view; analysis of the patellar component employs five zones (Zone 1 – Zone 5) in the Merchant view. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width is defined as radiolucency present.

Subsidence is defined as settling of the prosthetic component in bone, and is related to the distance between fixed bony landmarks on the tibia and the prosthesis. It should be noted that Knee Society guidelines state that direct subsidence without angular movement cannot be detected because there is no reference point.[14]

Surgical Details:

Intraoperative data collected includes, but may not be limited to, the duration of surgery, tourniquet time, blood loss, units of blood transfused, anesthesia used, prophylaxis, surgical technique, surgical approach, soft tissues released, implanted prostheses and complications.

2.2 Safety

All operative site events occurring at any time, as well as all serious adverse events (SAEs) occurring in the perioperative period (intraoperative to hospital discharge), are collected and compared to published data. It is expected that the AE rates reported for the Triathlon Tritanium Tibial Baseplate and Patella will be comparable to those reported in the literature for cemented primary total knee systems on the market. Details regarding AE definitions, recording and reporting are in Section 8 of this protocol, Adverse Events.

3 Clinical Study Plan

3.1 Study Design

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

3.2 Number of Centers

3.2.1 Centers for Standard Data Collection

Cases are to be enrolled at five to ten centers. The same center may be included in both arms. Conversely, a center may choose to participate in only a single arm. The enrollment goal is approximately 36 - 72 cases per center for Cohort 1 (cementless) and 15 - 30 cases per center for Cohort 2 (cemented) , and 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.

3.3 Number of Subjects

Cases are enrolled in the Cohort 1 (cementless) until a total of 356 cases receive the Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella, Triathlon CR or PS Beaded Femur with PA and the Triathlon Tibial Insert. All components in this cohort must used in a cementless application. Enrollment in Cohort 2 (cemented) will begin upon completion of enrollment into the Cohort 1 (cementless), and will continue until a total of 144 cases receive the Triathlon Tibial Tray, Triathlon Patella, Triathlon CR or PS Femur and Triathlon Tibial Insert. All components in this cohort must be used in a cemented application.

3.4 Estimated Study Duration

The enrollment period is estimated to be 24 months; cases for Cohort 1 (cementless) are evaluated as per the evaluation schedule until each case reaches 10 years. Cases for Cohort 2 (cemented) are evaluated as per the evaluation schedule until each case reaches 5 years. The total is estimated study duration from enrollment to close-out activities is 12 years.

To allow for a learning curve with the use of the device, enrollment of cases into the study commences when three cases have been completed at the center using the Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella.

4 Eligibility

The following criteria are used to distinguish patients eligible for enrollment into this study. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and preoperative level of health, as well as the surgeon's experience and familiarity with the device.

4.1 Inclusion Criteria

1. Patient has signed an IRB/EC approved; study specific Informed Patient Consent Form.
2. Patient is a male or non-pregnant female age 18 – 75 years at time of study device implantation.
3. Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
4. Patient is a candidate for primary cementless total knee replacement, including a resurfaced patella.
5. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

4.2 Exclusion Criteria

1. Patient has a Body Mass Index (BMI) > 40.
2. Patient has a diagnosis of avascular necrosis or inflammatory arthritis.
3. Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation.
4. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device.
5. Subject is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's Disease) leading to progressive bone deterioration.
6. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days).
7. Patient is diagnosed with lumbar radicular pain.
8. Patient has a known sensitivity to device materials.
9. Patient is a prisoner.

5 Subject Enrollment

5.1 Treatment Assignment

All subjects in Cohort 1 (cementless) will receive the Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella, Triathlon CR or PS Beaded Femur with PA and the Triathlon Tibial Insert. All components in Cohort 1 (cementless) must be used in a cementless application.

All subjects in Cohort 2 (cemented) will receive the Triathlon Cemented Tibial Baseplate, Triathlon Cemented Patella, Triathlon CR or PS Cemented Femur and the Triathlon Tibial Insert. All components in Cohort 2 (cemented) must be used in a cemented application.

Patients will be enrolled until 356 subjects are implanted with the study device in Cohort 1 (cementless) and 144 subjects are implanted with the control device in Cohort 2 (cemented). Patients will not count toward enrollment unless they receive all components and use them as indicated per the protocol for the specified study cohort.

5.2 Randomization

The study will enroll under a non-randomized concurrent control study design. Cohort 1 (cementless) and Cohort 2 (cemented) will be enrolled contemporaneously. In the event the same center participates in both arms a consecutive series of patients will be enrolled into Cohort 1 (cementless) until the enrollment objective is met before commencement of enrollment of patients into Cohort 2 (cemented).

6 Device Description

6.1 Study Device

The Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella, Triathlon CR or PS Beaded Femur with PA and the Triathlon Tibial Inserts have been cleared for use in the United States; therefore, this study is considered a post-market assessment. All cases in Cohort 1 (cementless) must receive the Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella, Triathlon CR or PS Beaded Femur with PA and the Triathlon Tibial Insert.

The Triathlon Tritanium Tibial Baseplate features the Tritanium advanced fixation technology that closely resembles the porous structure of trabecular bone to promote biologic fixation. The Triathlon Tritanium Tibial Baseplate, the porous coating, solid keel, and solid pegs are built via Laser Rapid Manufacturing (LRM) with CP Titanium powder within a build envelope, and simultaneously bonded/melded onto a titanium alloy (Ti6Al4V ELI) substrate. CP Titanium powder is spread on top of the Ti6Al4V ELI substrate which is fixed to a piston inside the chamber. The laser beam is controlled and focused by computer to the powder bed. An argon

atmosphere is maintained within the chamber to prevent oxidation of the part during manufacturing.

The Triathlon Tritanium Tibial Baseplate is available in eight sizes and is coupled with the Triathlon Tritanium Patella which is available in five asymmetric sizes and four symmetric sizes. These components are coupled with the existing Triathlon CR or PS beaded femoral components and the N2VAC or X3 Triathlon Tibial Inserts. The combination of the Tritanium biologic fixation technology and the Triathlon Knee System design creates a two-tier high performance total knee system to provide surgeons with options for enhanced cementless knee fixation and joint stability which may meet the needs of today's younger and more active TKA patients. A description of the study device (Triathlon Tritanium Tibial Baseplate and Triathlon Tritanium Patella) follow. Appendix I provides a listing of all protocol-specified components. The catalog numbers for the study device are listed in Table 1 and Table 2.

Triathlon Tritanium Tibial Baseplate:

The catalog numbers for the Triathlon Tritanium Tibial Baseplate permissible according to this study protocol will be in the following format, where 'XXX' varies by size:

5536-B-XXX

Triathlon Tritanium Patella:

The catalog numbers for the Triathlon Tritanium Patella permissible according to this study protocol will be in the following format, where 'XXX' varies by size:

5552-L-XXX (asymmetric)

5556-L-XXX (symmetric)

Figure 1: Triathlon Tritanium Tibial Baseplate and Patella

Additionally, only the following **Stryker compatible** ancillary devices are to be used for Cohort 1 (cementless), according to this study protocol:

- Triathlon CR Beaded Femur with PA
- Triathlon PS Beaded Femur with PA
- Triathlon Tibial Inserts

The compatible Stryker components are listed in the surgical protocol.

For reference, a description of the compatible femoral components and tibial inserts follow. Appendix I provides a listing of all protocol-specified components. In the case of any uncertainty regarding device compatibility, the current version of the Triathlon Tritanium Knee System surgical protocol should be reviewed.

Triathlon CR and PS beaded Femur:

The catalog numbers for the Triathlon CR and PS beaded Femur permissible according to this study protocol will be in the following format, where 'XXX' varies by size:

5516-F-XXX (PS femur)

5517-F-XXX (CR femur)

Triathlon Tibial Inserts:

The catalog numbers for the Triathlon Tibial Inserts permissible according to this study protocol will be in the following format, where 'XXX' varies by size:

5530-P-XXX (CR insert, conventional polyethylene)

5530-G-XXX (CR insert, X3)

5531-P-XXX (CS insert, conventional polyethylene)

5531-G-XXX (CS insert, X3)

5532-P-XXX (PS insert, conventional polyethylene)

5532-G-XXX (PS insert, X3)

6.2 Control Device

All study subjects that are part of Cohort 2 (cemented) concurrent control group will receive the Triathlon Cemented Tibial Baseplate, Triathlon Cemented Patella, Triathlon CR or PS Cemented Femoral Component, and Triathlon Tibial Inserts. The Triathlon Total Knee System components have been cleared in the United States under the following 510(k) numbers: Triathlon Cemented Femur (K042993), Tibial Inserts (K051146 and K050539), Triathlon Tibial Baseplate (K031729), Triathlon Patella (K040267). These components are intended for cemented application. Appendix I provides a listing of all protocol-specified components.

The Triathlon Cemented Tibial Baseplate is fabricated from cast cobalt-chromium-molybdenum alloy. The Triathlon Cemented Tibial Baseplate is neutral in configuration, and is available in eight proportional sizes. The undersurface of the tibial tray and the keel is grit blasted for interdigitation with polymethylacrylate (PMMA) bone cement. The keel of the tibial tray is designed with normalizations for rotational stability and cement interdigitation. The superior aspect of the tibial tray has a rim that contains tabs that mate with the outer periphery of the tibial insert, along with the locking wire used on the tibial insert. This locking feature is designed to provide secure attachment of the tibial insert to the tray, and is designed to reduce micromotion of the tibial insert on the tray.

The Triathlon Cemented Patella components are available in two styles, symmetric and asymmetric. Both are fabricated from either N2VAC UHMWPE or X3 UHMWPE. The symmetric design is available in six diameters (27 mm, 29 mm, 31 mm, 33 mm, 36 mm, and 39 mm) and four thicknesses (8 mm, 9 mm, 10 mm, and 11 mm). The symmetric design features a central cement recess, and three pegs on the bone interface surface. The Triathlon Symmetric

Patellar component is intended to be implanted via a resurfacing or inset surgical technique. The asymmetric design features a flare in the lateral aspect of the component. The asymmetric patellar component also has a central recess with three pegs for cement fixation.

The Triathlon Cemented Femur is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. It is available in right and left configurations, and eight proportional sizes (sizes 1 to 8) to accommodate differences in patient anatomy. The interior surface of the component is grit-blasted to increase the surface roughness – this is intended to promote interdigitation of the PMMA bone cement with the surface texture and the apposing bone.

6.3 Device Retrieval Process

Stryker Orthopaedics will retrieve the Triathlon Tritanium Tibial Baseplate and/or Patella and/or adjacent tissues for analysis to help characterize potential device-related complications. In the event that the Triathlon Tritanium Tibial Baseplate and/or Patella are removed from a study subject, the procedure outlined in the Retrieved Implant Analysis Protocol (Appendix C) should be followed. In addition:

1. 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.
2. Stryker Clinical Research will send a retrieval container to the SC.
3. After the device is explanted, the SC or an identified Stryker field representative will retrieve the device and place it in the retrieval container, following the instructions in Appendix C.
4. The SC, an identified field representative or Stryker Clinical Research will complete a Product Experience Report (PER).
5. If not completed by Stryker Clinical Research, the PER should be faxed or emailed to Stryker Product Surveillance at 201-831-6775 or soprodexreports@stryker.com, as well as to Stryker Clinical Research at 201-831-6454 or to the Clinical Research email addresses listed on the Sponsor Contact Sheet.
6. The PER should be attached to the retrieval container and sent to Product Surveillance. A de-identified operative report should be included, when available.

7. Stryker Clinical Research will follow up with Product Surveillance to obtain a PER number.
8. A summary of results will be provided to the investigator upon his/her request.

7 Evaluations

7.1 Preoperative Visit

During the preoperative visit, patients that are possible candidates for this study are screened to determine if they meet the inclusion/exclusion criteria. If the patient is a candidate, the investigator proposes participation in the study to the patient, according to GCP guidelines. Patients must sign an IRB/EC approved Informed Patient Consent Form prior to participating in any study related activities. Consent must be obtained within 4 months prior to surgery. 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 preoperative data collection, the subject will need to be re-consented, all preoperative data will need to be re-collected and all original preoperative data will need to be removed from the database.

Once the patient has been consented, preoperative data will be collected including: demographics and medical history, 2011 KSS, OKS, SF-12, AP, ML and Merchant radiographs for both Cohort 1 (cementless) and Cohort 2 (cemented).

All preoperative data must be collected within 4 months prior to the scheduled date of surgery, with the exception of radiographs, acceptable within 1-year prior to the scheduled date of surgery. All information collected preoperatively will be used to quantify the sample population and compare postoperative progress. 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 preoperative data collection, the subject will need to be re-consented, as noted above.

7.2 Surgery

Surgical details will be collected from the operative notes and at the time of surgery for both Cohort 1 (cementless) and Cohort 2 (cemented).

7.3 6-week Visit

During the 6-week visit (± 3 weeks), the following evaluations will be collected: 2011 KSS, OKS, SF-12, AP, ML and Merchant radiographs for both Cohort 1 (cementless) and Cohort 2 (cemented).

7.4 6-month Visit

During the 6-month visit (- 14 - + 4 weeks), the following data will be collected: 2011 KSS, AP, ML and Merchant radiographs for both Cohort 1 (cementless) and Cohort 2 (cemented).

7.5 Annual Follow-up Visits

7.5.1 Cohort 1 (cementless) Annual Follow-up Visits

Cohort 1 (cementless) will be followed to 10 years postoperatively according to the following schedule. Clinical data will be collected via office visit by the investigator at the following annual postoperative intervals: 1-year, 2-year 5-year and 10-year. Tools for postoperative evaluation at each of these intervals will be the 2011 KSS, OKS, SF-12, AP, ML and Merchant radiographs. In the event that an in-person visit cannot be conducted and radiographs cannot be obtained, a Follow-up Questionnaire will be completed via mail, online completion (if available), or subject telephone interview with the subject by investigative site personnel.

The Follow-up Questionnaire, OKS and SF-12 will also be collected at the 3-year, 4-year, 6-year, 7-year, 8-year and 9-year intervals via mail, online completion (if available), or subject telephone interview with the subject by investigative site personnel. The questionnaire is used to obtain information on satisfaction, pain, complications and any study device revisions to enable calculation of the Kaplan-Meier Survival Curves.

All clinical data, radiographs, and patient outcomes data must be collected within ± 2 months of the 1-year and 2-year anniversary dates. For remaining annual time points, the window expands to ± 3 months of the 3-year anniversary date and ± 4 months of the 4-year through

10-year anniversary dates.

7.5.2 Cohort 2 (cemented) Annual Follow-up Visits

Cohort 2 (cemented) will be followed to 5 years postoperatively according to the following schedule. Clinical data will be collected via office visit by the investigator at the following annual postoperative intervals: 1-year, 2-year and 5-year. Tools for postoperative evaluation at each of these intervals will be the 2011 KSS, OKS, SF-12, AP, ML and Merchant radiographs. In the event that an in-person visit cannot be conducted and radiographs cannot be obtained, a Follow-up Questionnaire will be completed via mail, online completion (if available), or subject telephone interview with the subject by investigative site personnel.

The Follow-up Questionnaire, OKS and SF-12 will also be collected at the 3-year and 4-year intervals via mail, online completion (if available), or subject telephone interview with the subject by investigative site personnel. The questionnaire is used to obtain information on satisfaction, pain, complications and any study device revisions to enable calculation of the Kaplan-Meier Survival Curves.

All clinical data, radiographs, and patient outcomes data must be collected within ± 2 months of the 1-year and 2-year anniversary dates. For remaining annual time points, the window expands to ± 3 months of the 3-year anniversary date and ± 4 months of the 4-year and 5-year anniversary dates.

8 Adverse Events

8.1 Reporting of Adverse Events

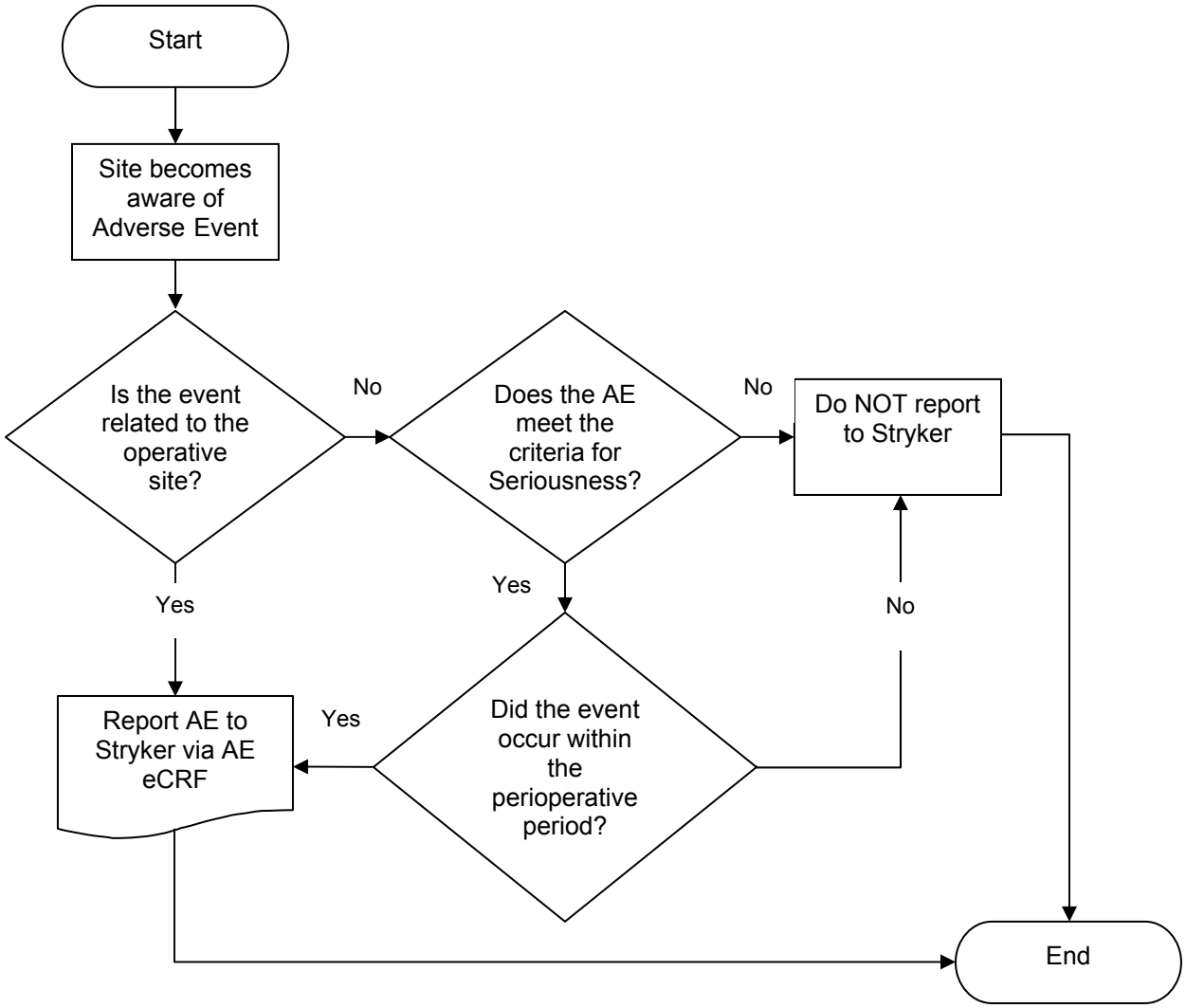
The AE reporting requirements for this study are as follows:

- All AEs that are operative site related, regardless of seriousness or time of occurrence.
- All AEs that meet the definition of serious and occur within the perioperative period (intraoperative to hospital discharge)

On postoperative functional evaluations, investigators and SCs are 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.

Additionally, SCs are responsible for following up with the subjects regarding any questionable responses received on the Follow-up Questionnaire. If it is determined upon this further investigation that a protocol-defined AE has occurred, the SC will be responsible for completing an AE eCRF, submitting the event to Stryker and reporting to the IRB/EC, as required.
The following decision tree facilitates identification of AEs for which reporting is required under this study protocol:

Figure 2: 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.

8.2 General Adverse Event Definitions

Following is a list of general AE definitions. For the purposes of this study, only SAEs occurring in the perioperative period, excluding elective procedures at any time, 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 8.1, 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 12, 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.

8.3 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 AE 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 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.

An AE eCRF must be completed within 24 hours. If a SAE occurs during the perioperative period, the de-identified source documentation must be uploaded to the appropriate location within Stryker's Electronic Data Capture (EDC) system within 24 hours of the investigative center's SAE awareness. See Section 11, Data Management, for additional details of Stryker's EDC system. These reports will be evaluated by Stryker to determine if a PER is required.

It is recommended that all other reportable AEs are submitted through eCRF entry within 2 weeks of becoming aware of the event.

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

8.3.1 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 reporting requirements. Copies of each report and documentation of EC/IRB notification and receipt must be kept with the investigator's study files.

8.4 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 or until it is determined at the end of the study that the AE will not resolve.

8.5 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 PER System.

9 Statistical Plan

9.1 Efficacy

9.1.1 Primary Efficacy Parameters

The primary efficacy parameter is the success rate at 2 years postoperative with the Triathlon Tritanium Tibial Baseplate for Cohort 1 (cementless), where success is defined as absence of tibial baseplate revision and/or removal for aseptic loosening at 2 years postoperative.

9.1.2 Secondary Efficacy Parameters

The secondary efficacy parameters include:

- The all-cause survivor function of the Triathlon Tritanium Tibial Baseplate by Kaplan-Meier method for Cohort 1 (cementless).
- The all-cause survivor function of the Triathlon Tritanium Patella by Kaplan-Meier method for Cohort 1 (cementless).
- The all-cause revision and/or removal rate of the Triathlon Tritanium Tibial Baseplate for Cohort 1 (cementless).

- The all-cause revision and/or removal rate of the Triathlon Tritanium Patella for Cohort 1 (cementless).
- 2011 KSS, SF-12 and OKS scores at 2 year for both cohorts.

9.1.3 Primary Efficacy Analysis

The primary hypothesis to be tested will be that the success rate at 2 years postoperative with the Triathlon Tritanium Tibial Baseplate for Cohort 1 (cementless) is not worse than 99% with a non-inferiority margin of 2%.

That is, the following hypothesis will be tested:
H_0: Pt <= 99% - 2% H_A: Pt > 99%- 2%

Here, Pt is the success rate at 2 years postoperative with the Triathlon Tritanium Tibial Baseplate for Cohort 1 (cementless).

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 97%, then the non-inferiority hypothesis will be supported.

9.1.4 Secondary Efficacy Analysis

For Cohort 1 (cementless), the all-cause survivor function of the Triathlon Tritanium Tibial Baseplate will be produced by Kaplan-Meier method; The all-cause survivor function of the Triathlon Tritanium Patella will be produced by Kaplan-Meier method; The all-cause revision and/or removal rate of the Triathlon Tritanium Tibial Baseplate will be calculated; The all-cause revision and/or removal rate of the Triathlon Tritanium Patella will be calculated. The 2011 KSS, SF-12 and OKS scores will be compared between Cohort 1 (cementless) and Cohort 2 (cemented) at 2 years postoperative using applicable statistical methods.

9.2 Safety

9.2.1 Safety Parameters

Safety parameters include all protocol-defined AEs as well as revision and/or removal rates. For details regarding protocol-defined AEs, see Section 8.1.

9.2.2 Safety Analyses

The frequency and percentage of all protocol-defined AEs will be tabulated. For details regarding protocol-defined AEs, see Section 8.1.

9.3 Missing Data

Missing data in OKS will be imputed when calculating the OKS score using the method recommended by the new OKS scoring system.[15] Missing data in 2011 KSS will be imputed when calculating KSS scores with the method recommended in the user manual of the 2011 Knee Society knee scoring system.[16] No other missing data will be imputed.

9.4 Statistical Methodology

9.4.1 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).

A Kaplan-Meier survivorship curve will be displayed for revision and/or removal of the Triathlon Tritanium Tibial Baseplate for aseptic loosening for cementless cohort.

For the additional data collected according to Section 2.1.3, data will be summarized according to visits and cohorts. 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 from

Demographics), the frequency and percentage in each category will be presented. A paired t-test will be performed to evaluate the change in clinical and patient outcomes, preoperative to 10 years for cases with the Triathlon Tritanium Tibial Baseplate in cementless cohort. The 2011 KSS, OKS, and SF-12 will be compared and be presented with respect to improvement from preoperative to postoperative scores for both cohorts when applicable.

For the Follow-up Questionnaire, frequency and percentage will be computed for each category according to visits and cohorts. Applicable lists based on the Follow-up Questionnaire will be generated to capture AEs.

For radiographic data, data will be presented according to visits and cohorts for available parameters. Frequency and percentage will be computed for radiolucency according to visits. Radiographs will be evaluated according to the guidelines of The Knee Society total knee arthroplasty roentgenigraphic evaluation and scoring system.[13]

Documentation of statistical analyses will utilize SAS software version 9.1.3 or higher.

9.4.2 Sample Size Justification

With a reference value of 99% for the success rate at 2 years, under the assumptions of 5% significance level (or 95% one-sided confidence interval), 95% power, 2% non-inferiority margin, the sample size is 267. After factoring a 15% lost to follow-up rate, the final sample size is 315 for the primary endpoint. An enrollment objective of 356 cases in Cohort 1 (cementless) was selected to power the primary objective of this study. In addition, 144 cases will be enrolled in Cohort 2 (cemented) to serve as a concurrent control for one of the secondary objectives.

9.4.3 Interim Analyses

No interim analysis is planned.

9.4.4 Analysis Population

Per Protocol Population: The study population for analysis will include all non-censored subjects who receive the study devices and are available for efficacy evaluation. For details regarding study devices, see Section 6.1 and 6.2.

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 the study devices. For details regarding study devices, see section 6.1 and 6.2. For details regarding protocol-defined AEs, see Section 8.1.

The safety analysis will be based on the safety population.

10 Study Procedures

10.1 Subject Recruitment and Screening

Patients are recruited at the study centers during preoperative visits through normal referral patterns. All patients recruited for this study must have the capacity to give informed consent. 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 D

10.2 Patient Informed Consent and Guidelines

All patients for this study are 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 E for a copy of the Model Informed Patient Consent. This is 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 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.

10.3 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 is 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 for each treatment group:

- Cohort 1 (cementless)
  - Triathlon Tritanium Tibial Baseplate
  - Triathlon Tritanium Patella
  - Triathlon CR or PS Beaded Femur with PA
  - Triathlon Tibial Insert

- Cohort 2 (cemented)
  - Triathlon Cemented Tibial Baseplate
  - Triathlon Cemented Patella
  - Triathlon CR or PS Cemented Femur
  - Triathlon Tibial Insert

Revision or removal of the Triathlon Tritanium Tibial Baseplate for aseptic loosening constitutes a failure for purposes of the primary endpoint. Revision or removal of the Triathlon Tritanium Tibial Baseplate for any reason requires study termination for the subject.

If revision of the Triathlon Tritanium Patella, Triathlon Beaded Femur or Triathlon Tibial Insert component is required during the study, the event does not constitute a failure or study termination for Cohort 1 (cementless). If revision of the Triathlon Cemented Patella, Triathlon Cemented Femur or Triathlon Tibial Insert component is required during the study, the event does not constitute a failure or study termination for Cohort 2 (cemented).

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, and 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 preoperative data collection, the subject will need to be re-consented, all preoperative data will need to be re-collected and all original preoperative data will need to be removed from the database. 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.

11 Data Management

11.1 Database

Data will be collected at each center and entered into Stryker's 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 F

11.2 Confidentiality

This study complies with the 2002 HIPAA privacy rule. As such, Stryker only collects that information which is necessary to support the objectives of the clinical study. Stryker takes precautions to ensure that data received is as de-identified as possible. In the case that some identified information is received, Stryker ensures 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.

11.3 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 13, compare the eCRFs against source documents for accuracy. The monitors 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.

11.4 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.

11.5 Data Clarification Requests

If errors or omissions are noted by Stryker upon review of the data entered into the eCRFS, a data clarification request (DCR) is sent to the center within the EDC system. Queries should be answered in a clear and comprehensible manner. If the clarification requires a change to study data, the EDC system updates the eCRF automatically with the data captured in the DCR response. Conversely, a change to the data that brings it within the expected range of values will automatically close the DCR. The investigative center is required to reapply their electronic signature to the modified eCRF. Modified eCRFs need not be printed and included in conjunction to answered DCRs.

11.6 Protocol Deviations

Any deviation from this protocol is 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. 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.

11.7 Records Retention

It is the investigator's responsibility to retain study essential documents for 2 years after the date of the final report, or in the case of non-compliance, 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.

12 Risk/Benefit Assessment

12.1 Risk Category

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

12.2 Potential Risk

The study involves the routine assessment of a primary TKA procedure. The study device has been cleared for use by the FDA and will be used according to its labeling, included in Appendix G. 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 primary 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/or 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, patella or tibia can occur due to impaction of the component into the prepared femur, patella or tibia. Postoperative femoral, patellar 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.

12.3 *Expected Complications*

Complications associated with TKA procedures, such as those performed with the study device, have been reported. These complications include but are not limited to: infection, genitourinary, gastrointestinal disorders, vascular disorders, bronchopulmonary disorder, myocardial infarction, injury to the knee's neurovascular structures, loosening of the components, osteolysis, heterotopic bone formation, deep vein thrombosis, pulmonary embolism, metal sensitivity reactions, intraoperative or postoperative fracture of the femur, patella or tibia, and the need for re-operation, revision, arthrodesis of the involved joint, amputation of the limb and death. The safety analysis will include tabulation of AE rates as well as revision/removal rates.

12.4 Protection Against Risks

Subjects are treated in the best medical judgment of the investigator, regardless of the study protocol. If an investigator must deviate from the written protocol to protect the health or well being of the subject, this deviation is promptly reported to both the EC/IRB and Stryker.

12.5 Potential Benefits to the Subject

There is no guarantee that subjects 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.

13 Study Monitoring, Auditing, and Inspecting

13.1 Study Monitoring Plan

Monitors are persons employed by sponsors to review the conduct of clinical studies to assure that the clinical investigators abide by their obligations to conduct clinical 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.

This study is monitored at least once per year, with additional monitoring as necessary. The investigator allocates adequate time for such monitoring activities. The investigator also ensures 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 reviews all source documents and compares 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 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

13.2 Auditing and Inspecting

A quality assurance audit is a form of review that provides additional confidence to the sponsor concerning the validity and accuracy of clinical study data that 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 permits 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 ensures the capability for inspections of applicable study-related facilities.

14 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 are to 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 is made in writing to the investigator and a copy of this decision is 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 are 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.

15 Study Finances

15.1 Funding Source

This study is financed by Stryker Orthopaedics.

15.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (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.

15.3 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 from Stryker. 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 are not 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

Under extreme circumstances, and with prior approval, Stryker may reimburse a subject for the cost of transportation to and from the investigator's office for a protocol-required office visit.

This policy is the same for all participating study subjects and does not bias against any particular subject or study cohort.

16 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, 5 and 10 years of follow-up. Early results with regard to surgical information, postoperative biomechanics and early radiographic assessments 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.

Publications will be facilitated by the Chair and the primary investigator (PI) of the study. Both individuals will be chosen by Stryker.

The PI is solely focused on the multi-center publications and progress towards those publications, including recurring updates to centers, center motivation as well as authorship. If the PI does not produce a draft of a publication within 90 days of receiving the results data, Stryker will delegate the responsibility to other investigators in the study at its discretion.

The Chair reviews all additional publications proposed by participating investigators based upon the study results prior to study completion, on an ongoing basis. This review includes whether or not a proposal will be pursued, as well as imposition of guidelines as to publication completion and criteria.

The following summarizes the possible roles of these parallel positions:

Chair	PI
Contributes to study design	Contributes to study design
Assists with study questions requiring expert clinical opinion	Assists with study questions requiring expert clinical opinion
Assists with identification of investigators	Assists with identification of investigators and maintains performance
Reviews additional publication proposals submitted by investigators	Updates investigators on progress towards multi-center results
Contributing author, if ICMJE guidelines met	Primary author, multi-center publication of primary endpoint data

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, 5 and 10-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.

17 References

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Appendix A

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

May 3, 2013

Homedica Osteonics Corporation
% Ms. Audrey Witko
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K123486
Trade/Device Name: Triathlon® Tritanium® Tibial Baseplates
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: April 26, 2013
Received: April 29, 2013

Dear Ms. Witko:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K123486

Device Name: Triathlon® Tritanium® Tibial Baseplates

Indications for Use:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory 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 Stabilizing (PS) 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

The Triathlon® Tritanium® Tibial Baseplates are indicated for both cemented and uncemented use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

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

November 26, 2013

Stryker Orthopaedics
Ms. Shikha Khandelwal
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K132624
Trade/Device Name: Triathlon® Tritanium® Metal-Backed Patella
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: August 29, 2013
Received: August 30, 2013

Dear Ms. Khandelwal:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

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

Enclosure

Indications for Use

510(k) Number (if known): K132624

Device Name: Triathlon® Tritanium® Metal-Backed Patella

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.

The Triathlon® Tritanium® Tibial Baseplate and Tritaium® Metal-Backed Patella 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

MAY - 5 2004

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. DBA (doing business as) Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. (DBA Stryker Orthopaedics) 325 Corporate Drive Mahwah, New Jersey 07430

Device Identification

Proprietary Name:	Triathlon™ Cruciate Retaining (CR) Total Knee System
Common Name:	Cruciate Retaining Total Knee Replacement
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

The Triathlon™ CR Total Knee System consists of a femoral component, tibial insert, and all-polyethylene patellar components that are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ All Polyethylene Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System, as well as the previously released Triathlon™ PS Femoral component in

situations where replacement of the articular surface of the patella is required. The Triathlon™ CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Triathlon™ Cruciate Retaining (CR) Total Knee System consists of three primary components: Triathlon™ Cruciate Retaining (CR) Femoral Component, Triathlon™ Cruciate Retaining (CR) Tibial Insert, and Triathlon™ Patellar components (available in two styles – symmetric and asymmetric). These components are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ Patellar components are intended to be used with both the Triathlon™ CR Femoral component, the previously cleared Triathlon™ PS Femoral component, or the femoral components of the Duracon® Total Knee System. Duracon® patellar components may be used with both the Triathlon™ PS and Triathlon™ CR femoral components. The use of a patellar component is optional. The Triathlon™ CR components are described below:

The Triathlon™ Total Knee Cruciate Retaining (CR) Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. This cruciate retaining femoral component is utilized when total knee replacement is indicated, and accommodates the posterior cruciate ligament if it is present.

The Triathlon™ Total Knee Cruciate Retaining (CR) Femoral Component is available in right and left configurations, and eight proportional sizes (sizes 1 to 8) to accommodate differences in patient anatomy. The interior surface of the component is grit-blasted to increase surface roughness - this is intended to promote interdigitation of the polymethylmethacrylate (PMMA) bone cement with the surface texture and the apposing bone. This femoral component features cast-in pegs to help in femoral component placement, and to provide rotational stability.

The Triathlon™ Cruciate Retaining (CR) Tibial Insert is neutral in configuration, and is available in seven proportional sizes (sizes 2 to 8) and varying thicknesses (9mm, 11mm, 13mm, 16mm, and 19mm). The insert is fabricated from ultra high molecular weight polyethylene and cobalt-chromium alloy. The minimum thickness of the tibial insert on the bearing surface is 6mm. The tibial insert is designed to accommodate the posterior

cruciate ligament if it is present. There is a relief on the anterior aspect of the tibial insert to accommodate the patellar tendon and patellar fat pad.

The Triathlon™ CR Tibial Insert incorporates a locking wire feature on the anterior aspect of the insert. This locking wire is fabricated from cobalt-chromium alloy, and engages under tabs on the anterior rim of the Triathlon™ Primary Tibial Baseplate. This wire-tab locking mechanism secures the insert into the baseplate. This insert-baseplate locking mechanism is identical to the locking mechanism utilized on the Triathlon™ PS Total Knee System.

Triathlon™ Patellar components are available in two styles: symmetric and asymmetric. Both are fabricated from ultra high molecular weight polyethylene. The symmetric design is available in six diameters (27mm, 29mm, 31mm, 33mm, 36mm, and 39mm) and four thicknesses (8mm, 9mm, 10mm, and 11mm). The symmetric design features a central cement recess, and three pegs on the bone interface surface. The Triathlon™ Symmetric patellar component is intended to be implanted via a resurfacing or inset surgical technique. The asymmetric design is available in five superior/inferior dimensions (29mm, 32mm, 35mm, 38mm, and 40mm) and three thicknesses (9mm, 10mm, and 11mm). The asymmetric design features a flare on the lateral aspect of the component. The asymmetric patellar component also has a central recess with three pegs for cement fixation. The Triathlon™ Asymmetric patellar component is intended to be implanted using a resurfacing surgical technique.

Equivalent products include:

1. Triathlon™ PS Total Knee System
2. Duracon® CR Femoral Component
3. Scorpio® CR Femoral Component
4. Duracon® A/P Lipped Tibial Insert
5. Duracon® Symmetric Patellar Component
6. Duracon® Asymmetric Patellar Component
7. Kinemax® All Polyethylene Patella

Testing was presented to support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K040267
Trade/Device Name: Triathlon™ Cruciate Retaining (CR) Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 4, 2004
Received: February 5, 2004

Dear Ms. Crowe:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040267 (pg 1 of 2)

Indications for Use

510(k) Number (if known): K040267

Device Name: Triathlon™ CR Total Knee System

Indications For Use:

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

510(k) Number K040267

The Triathlon™ CR Total Knee System consists of a femoral component, tibial insert, and all-polyethylene patellar components that are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ All Polyethylene Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System, as well as the previously released Triathlon™ PS Femoral component in situations where replacement of the articular surface of the patella is required. The Triathlon™ CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

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

K040267 (pg 2 of 2)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K040267

JAN 12 2005

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 325 Commerce Court Mahwah, NJ 07430
For Information contact:	Denise Duchene Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Commerce Court Mahwah, NJ 07430

Device Identification

Proprietary Name:	Triathlon™ Posteriorly Stabilized (PS) Femoral Component (5515)
Common Name:	Posteriorly Stabilized Knee Femoral Component
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

It is the intention of Howmedica Osteonics Corp. to modify the design of the Triathlon™ Posteriorly Stabilized (PS) Femoral Component (previously released under K031729) to improve component manufacturability.

The design change for the Triathlon™ PS Femoral Component involves a removal of material from the superior, posterior region of the cam (or box) section of the femoral

component adjacent to the posterior femoral condyles. This material is being removed to improve manufacturability of the component. The articular surface designs of the component (both patello-femoral and tibio-femoral) are unchanged by this modification.

The intended use of the Triathlon™ PS Femoral Component is identical to that of the predicate: it is intended to be used with Triathlon™ PS tibial inserts, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.

- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The modified Triathlon™ PS Femoral Component (catalog number 5515) is identical to the previously released Triathlon™ PS Femoral Component in terms of intended use, material, and general design features. The only difference is the removal of material from the superior, posterior portion of the cam. Physical testing was performed to show that the component could withstand load over ten million cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Denise Duchene
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Commerce Court
Mahwah, New Jersey 07430

Re: K042993
Trade/Device Name: Triathlon™ Posteriorly Stabilized PS Femoral Component (5515)
Regulation Name: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/ metal/ polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 29, 2004
Received: November 1, 2004

Dear Ms. Duchene:

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) 276-0210. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042993 42

510(k) Premarket Notification– Triathlon™ PS Femoral Component (5515)

510(k) Number (if known): K

Device: Triathlon™ Posteriorly Stabilized (PS) Femoral Component (5515)

The Triathlon™ PS Femoral Component has undergone a design modification – material has been removed from the superior, posterior aspect of the cam. This design change has been made to improve the manufacturability of the component. The intended use of the Triathlon™ PS Femoral Component is: it is intended to be used with Triathlon™ PS tibial inserts, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. Specific indications:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament

for Mark A. Millerson

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

510(k) Number K042993

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K042993

MAR 2 9 2005

K050539

Page 1 of 2

Special 510(k) Summary

Proprietary Name:	Size 1 Triathlon™ Posterior Stabilized (PS) Tibial Insert
Common Name:	Modular Tibial Insert
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	87 JWH
Predicate Proprietary Name:	Triathlon™ PS Tibial Insert – Sizes 1
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 JWH
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Prepared:	March 21, 2005

Description/Technological Comparison

This premarket notification describes a modification to the articulating surface of the size 1 Triathlon™ Posterior Stabilized Tibial Insert. This insert is intended to be used with the size 1 Triathlon™ Primary Cemented Tibial Tray and the Triathlon™ PS Femoral component in primary or revision total knee arthroplasty. This size 1 tibial insert has been modified for improved rotational constraint with the size 1 insert.

Intended Use

The intended use of the size one Triathlon™ Posterior Stabilized Tibial Insert is the same as that of the predicate device described in premarket notification K031729 – it is intended for use with Triathlon™ Posterior Stabilized femoral components, Triathlon™

Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. The Posterior stabilized design is intended to substitute for the posterior cruciate ligament if it is absent or non-functioning.

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2005

Dr. Susan Krasny, Ph.D., RAC
Director, Regulatory Affairs and Clinical Research
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K050539
Device Name: Triathlon™ Knee System Posterior Stabilized (PS) Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 28, 2005
Received: March 2, 2005

Dear Dr. Krasny:

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.

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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-__. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050539

Device Name: Triathlon™ Knee System – Posterior Stabilized (PS) Tibial Inserts

Intended Use:

The intended use of the size one Triathlon™ Posterior Stabilized Tibial Insert is the same as that of the predicate device described in premarket notification K031729 – it is intended for use with Triathlon™ PS femoral components, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. Specific indications/contraindications are listed below (these are identical to the predicate):

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

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)

Miriam C. Provost

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

510(k) Number K050539

SEP - 2 2003

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	Triathlon™ Posteriorly Stabilized (PS) Total Knee System
Common Name:	Posteriorly Stabilized Total Knee Replacement
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

The Triathlon™ PS Total Knee system is comprised of a femoral component, tibial tray, and tibial insert that are intended to be used in total knee arthroplasty (if replacement of the articular surface of the patella is required, the Duracon® patellar components are compatible with the Triathlon™ components). The Triathlon™ PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. Specific indications and contraindications for the Triathlon™ PS Total Knee System are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Triathlon™ Posteriorly Stabilized Total Knee System consists of three primary components: Triathlon™ Posteriorly Stabilized (PS) Femoral Component, Triathlon™ Primary Cemented Tibial Baseplate, and Triathlon™ Posteriorly Stabilized (PS) Tibial Insert. Optional Triathlon™ Femoral Distal Fixation Pegs are also available. If replacement of the articular surface of the patella is required, the Duracon® patellar components are intended for use with the Triathlon™ Posteriorly Stabilized Femoral Components.

The Triathlon™ Total Knee Posteriorly Stabilized Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. This posteriorly stabilized femoral component is utilized when total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability.

The Triathlon™ Total Knee Posteriorly Stabilized Femoral Component is available in right and left configurations, and eight proportional sizes to accommodate differences in patient anatomy. The interior surface of the component (except the interior surface of the PS box) is grit-blasted to increase surface roughness - this is intended to promote interdigitation of the polymethylmethacrylate (PMMA) bone cement with the surface texture and the apposing bone. This femoral component features an intercondylar box that engages the mating tibial insert eminence at 45° to 60° (depending upon size of implant). The superior portion of the box is open. This open box design is intended to reduce contact on the tibial insert eminence, and in the case of intra-operative or post-operative femoral fracture, allow the surgeon to use a retrograde femoral nail to treat the fracture. There are threaded attachment features on the distal and posterior aspects of the femoral component. The threaded attachment feature on the distal aspect of the component is to allow the use of modular pegs.

The Triathlon™ Primary Cemented Tibial Tray is fabricated from cast cobalt chromium molybdenum alloy. The Triathlon™ Primary Cemented Tibial Tray is neutral in configuration, and is available in eight proportional sizes. The undersurface of the tibial tray and the keel is grit blasted for interdigitation with PMMA bone cement. The keel of the tibial tray is designed with normalizations for rotational stability and cement interdigitation. The superior aspect of the tibial tray has a rim that contains tabs that mate with the outer periphery of the tibial insert, along with the locking wire used on the tibial insert. This locking feature is designed to provide secure attachment of the tibial insert to the tray, and is designed to reduce micromotion of the tibial insert on the tray.

The Triathlon™ Posteriorly Stabilized (PS) Tibial Insert is neutral in configuration, and is available in eight proportional sizes and varying thicknesses (9mm, 11mm, 13mm, 16mm, 19mm, 22mm, and 25mm). The insert is fabricated from ultra high molecular weight polyethylene and cobalt-chromium alloy. The minimum thickness of the tibial insert on the bearing surface is 6mm. The tibial insert features a tibial eminence (or post) that provides anterior/posterior constraint in clinical situations where the posterior cruciate ligament is absent or non-functional. As previously noted, the tibial eminence contacts the cam of the femoral component at 45-60 degrees of flexion. There is a relief on the anterior aspect of the tibial insert to accommodate the patellar tendon and patellar fat pad.

The Triathlon™ PS Tibial Insert incorporates a locking wire feature on the anterior aspect of the insert. This locking wire is fabricated from cobalt-chromium alloy, and engages under tabs on the anterior rim of the Triathlon™ Primary Tibial Baseplate. This wire-tab locking mechanism secures the insert into the baseplate.

Triathlon™ Distal Femoral Fixation Pegs are made available separate from the Triathlon™ Posteriorly Stabilized Femoral Component. These distal femoral fixation pegs are an accessory to the Triathlon™ PS Femoral Component, and are optional for use. These pegs are designed to provide rotational stability, and to aid the surgeon in the placement

of the femoral component on the prepared distal femur. The Triathlon™ Distal Femoral Fixation Pegs are fabricated from wrought cobalt chromium alloy. The distal portion of the fixation peg is threaded to allow the peg to be assembled to the distal threaded hole in the Triathlon™ PS Femoral component. The proximal portion of the peg is recessed to allow the use of a wrench to assemble the peg into the femoral component.

Equivalent products include:

1. Duracon® Monolithic Stabilizer Femoral Component
2. Duracon® Cruciform Tibial Baseplate
3. Duracon® PS Lipped Tibial Insert
4. Scorpio® Posteriorly Stabilized (PS) Total Knee System
5. Series 7000 Standard Tibial Tray

Testing was presented to support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2003

Mr. William J. Cymbaluk
Vice President
Quality Assurance/Regulatory Affairs/Clinical Research
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K031729
Trade/Device Name: Triathlon™ Posteriorly Stabilized (PS) Total Knee System
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: June 3, 2003
Received: June 4, 2003

Dear Mr. Cymbaluk:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Triathlon™ Posteriorly Stabilized (PS) Total Knee System 510(k) Premarket Notification

510(k) Number (if known): K 031729

Device: Triathlon™ Posteriorly Stabilized (PS) Total Knee System

The Triathlon PS Total Knee system is comprised of femoral components, tibial trays, and tibial inserts that are intended to be used with the patellar components of the Duracon® system in primary and revision total knee arthroplasty. The Triathlon™ PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. Specific indications and contraindications for the Triathlon PS Total Knee System are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site

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510(k) Number K031729

1 of 2

- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- ♦ Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

The Triathlon™ PS Femoral Component and the Triathlon™ Primary Cemented Tibial Baseplate are intended to be implanted using bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031729

2 of 2

K051146 (pg. 1 of 2)

JUL 13 2005

510(k) Summary of Safety and Effectiveness

Device: Triathlon® X3™ UHMWPE Tibial Inserts and Patellar Components

Classification: 21 CFR 888.3560 – Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis

Product Code 87 JWH,

Predicate Devices: Triathlon® Tibial Inserts and Patellar

Contact Person: Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
(201) 831-5718
(201) 831-6038 (FAX)
karen.ariemma@stryker.com

Date Summary Prepared: May 3, 2005

The Triathlon® X3™ UHMWPE Posterior Stabilized and Cruciate Retaining tibial inserts and the Triathlon® X3™ UHMWPE Patellar components are intended to be used with the cemented Triathlon® PS and CR femoral components and cemented Triathlon® Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon® X3™ UHMWPE Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System The Triathlon® PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. The Triathlon® CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The all polyethylene Triathlon® X3™ UHMWPE Patellar components are intended for implantation with bone cement only.

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The device includes tibial and patellar components of a total knee system. These components are used for the replacement of the bearing and/or articulating surfaces of the proximal tibia and patella. Tibial inserts will be made in Cruciate Retaining and Posterior Stabilized designs. Patellar components will be made in both Asymmetric and Symmetric designs.

Summary of Data

A risk analysis and research and development testing have been performed to demonstrate equivalence of the subject products to the predicate devices. Testing and analysis includes material properties testing, wear testing, disassembly force evaluation, multi-axis fatigue testing, patella shear testing and finite element modeling of contact stresses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051146
Trade/Device Name: Triathlon® X3™ UHMWPE Tibial Inserts and Patellar Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 3, 2005
Received: May 4, 2005

Dear Ms. Ariemma:

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 north 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) 276-0210. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051146 (pg. 1 of 2)

510(k) Number (if known): _____

Device Name: Triathlon® Knee System

Indications for Use:

The Triathlon® X3™ UHMWPE Posterior Stabilized and Cruciate Retaining tibial inserts and the Triathlon® X3™ UHMWPE Patellar components are intended to be used with the cemented Triathlon® PS and CR femoral components and cemented Triathlon® Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon® X3™ UHMWPE Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System The Triathlon® PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. The Triathlon® CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The all polyethylene Triathlon® X3™ UHMWPE Patellar components are intended for implantation with bone cement only.

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.

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510(k) Number K051146

- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

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)

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Division of General, Restorative, and Neurological Devices

510(k) Number K051146

Appendix B

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.

- 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. Standard technique

   a. The subject should be supine with the knee in full extension and the leg positioned neutrally.
   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 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.

Refer to Figure 1 for an acceptable AP radiograph.

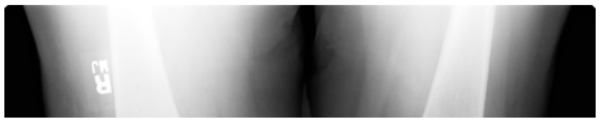

Figure 1. AP View - Acceptable

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.

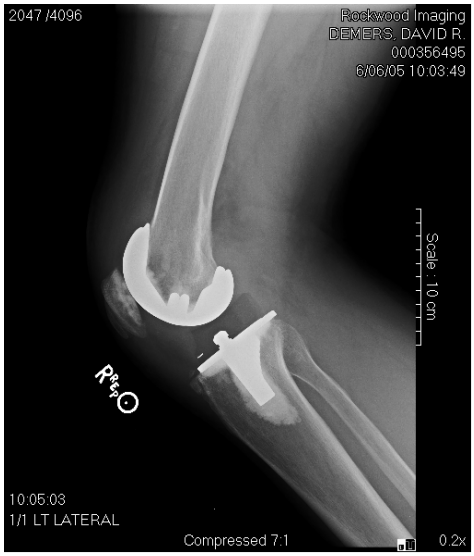

Figure 2. ML View - Acceptable

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

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

Appendix C

Retrieved Implant Analysis Protocol

RETRIEVED IMPLANT ANALYSIS PROTOCOL

Triathlon Tritanium Knee Outcomes Study

PURPOSE:

To evaluate retrieved Stryker Orthopaedics Triathlon Tritanium Tibial Baseplates, Triathlon Tritanium Patellae and other ancillary components and/or adjacent tissues 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 Knee Outcomes Study [510(k) clearance #K123486 – May 3, 2013 and 510(k) clearance #K132624 – November 26, 2013 will be asked to comply with the Retrieved Implant Analysis Protocol. Whenever possible, subjects who undergo revision/removal of the Stryker Orthopaedics Triathlon Tritanium Tibial Baseplate, Triathlon Tritanium Patella 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 E.

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 not signing 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 Tritanium Tibial Baseplate, Triathlon Tritanium Patella and/or ancillary component(s) obtained at the time of revision/removal should be placed in neutral buffered formalin. Any tissue samples submitted along with the implant must have been fixed in 10% 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 submitted along with the specimen.

Specimens should be carefully sealed and mailed by express mail to:

Stryker Orthopaedics
Attn: Loaner Dept, Dock K
325 Corporate Drive
Mahwah, NJ 07430

Recommendations for packing and shipping explants are attached to this protocol. Ensure a copy of the relevant PER is included with the specimen for appropriate identification of the component(s).

Recommendations for Packing and Shipping Explants To Stryker Orthopaedics

Please contact the Triathlon Tritanium Knee Outcomes Study CSM, identified on the Stryker Orthopaedics Contact Sheet, via phone to obtain an Exakt Pack Retrieval Shipping Container at least 1 week prior to scheduled revision/removal surgery.

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.

Using the Exakt Pack container as directed in the detailed Instructions For Use also acts to insulate any leakage from the shipping handlers.

Seal the shipping container securely. Send via express mail to:

Stryker Orthopaedics
Attn: Loaner Dept, Dock K
325 Corporate Drive
Mahwah, NJ 07430

RESULTS

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

Appendix D

Study Advertisements

Clinical Trial with the Triathlon Tritanium Tibial Baseplate and Patella

Dr. (name) of (practice) is participating in a clinical study evaluating a new primary knee replacement for cementless use in patients who are eligible for a primary total knee replacement.

The **Triathlon Tritanium Tibial Baseplate and Patella** are intended for cementless, press-fit use. They are compatible with other Stryker components as well. This baseplate and patella are currently being sold in the United States and are implanted in patients who need primary knee surgery.

Dr. (name) is one of 5 to 10 surgeons nationwide selected to enroll qualifying patients into this clinical study. The data collected will be used to evaluate both short and long-term (10-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 primary 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, 5 years and 10 years, and will be sent 3 questionnaires for completion at 3 years, 4 years, 6 years, 7 years, 8 years and 9 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 primary knee surgery.

Dr. (name)
Practice Name
Telephone Number

Study Coordinator Name
Title
Telephone Number

Appendix E

Model Informed Patient Consent

Informed Patient Consent

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

II. Description of the Study

You have been asked be in this research study because your doctor thinks you need surgery to replace your knee joint. About 500 people from up to 10 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 Tritanium Tibial Baseplate and Triathlon Tritanium Patella will be. These parts will be put in using no bone cement. The study will be able to tell how well the knee replacement parts work by looking at whether there is a need to remove or replace the baseplate because of the baseplate 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 that was put in using bone cement.

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 find out if the Stryker Orthopaedics Triathlon Tritanium cementless knee replacement works as well as a cemented 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.

This study has two sections that you can be in. These are called Cohort (Group) 1 and Cohort (Group) 2. Group 1 is made up of patients who get the Triathlon Tritanium cementless knee replacement. Group 2 is made up of patients who get a Triathlon CR or PS cemented knee replacement. Group 2 is called the control group. Your doctor will tell you if you will be in Group 1 or Group 2.

<u>Group 1- Cementless Knee Replacement</u>

If you are in Cohort 1 of the study, you will be in the study for the next 10 years. Your doctor will examine you before surgery and during surgery. Then he will examine for the study you again after your surgery. These exams will be 6 weeks, 3 months 1 year, 2 years, 5 years, and 10 years after your surgery.

During the visit before surgery you will need to fill out four forms about your health. Your doctor will also collect other information and x-rays that would be collected at a normal visit.

You will have surgery and your doctor will tell us the details of your surgery.

During your visits to the doctor 6 weeks, 3 months, 1 year, 2 years, 5 years, and 10 years after surgery, your doctor will figure out how well your knee is working. He will also take three 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 6 weeks, 1 year, 2 years, 5 years, and 10 years after surgery, your doctor will ask you to fill out three forms. At 3 months you will fill out one form. These forms will be about your health. You will also need to fill out three forms over the mail 3 years, 4 years, 6 years, 7 years, 8 years, and 9 years after your surgery.

Group 2- Cemented Knee Replacement

If you are in Group 2 of the study, you will be in the study for the next 5 years. Your doctor will examine you before surgery and during surgery. Then he will examine for the study you again after your surgery. These exams will be 6 weeks, 6 months 1 year, 2 years, and 5 years after your surgery.

During the visit before surgery you will need to fill out four forms about your health. Your doctor will also collect other information and x-rays that would be collected at a normal visit.

You will have surgery and your doctor will tell us the details of your surgery.

During your visits to the doctor 6 weeks, 3 months, 1 year, 2 years, and 5 years after surgery, your doctor will figure out how well your knee is working. He will also take three 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 6 weeks, 1 year, 2 years, and 5 years after surgery, your doctor will ask you to fill out three forms. At 3 months you will fill out one form. These forms will be about your health. You will also need to fill out three forms over the mail 3 years and 4 years after surgery.

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 make your knee work better. You will need to see your doctor at 6 weeks, 3 months, 1 year, 2 years, and 5 years after your surgery, and if you are in Group 1 also at 10 years after surgery, so your doctor can see if your knee replacement is doing well.

IV. Possible Risks

This study looks at how well a knee replacement works. It is typical for this kind of study. 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 knee surgery should be covered by your insurance carrier. You will not be paid to be in the study.

X. Device Retrieval Analysis Study

I understand that [Investigators Names] may need to take knee replacement parts out of my body during the study. If this happens, 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 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 agree to allow the Sponsor to study any knee replacement parts removed from me. 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.

_____ _____

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 make sure the company's knee replacement parts are working well. 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 F

Draft Specifications for Electronic Case Report Forms

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐
Patient Initials (if there's no middle initial please use a "-") ☐☐☐
Termination Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
Operative Side ☐Left ☐Right

Study Termination

1. Did subject complete study according to protocol (Please choose one):
    a. ☐ Yes
    b. ☐ No (if no, please select primary reason below)

2. Primary reason for termination (Please choose one):
    a. ☐ Screen failure
    b. ☐ Death
    c. ☐ Investigative site termination
    d. ☐ Lost to follow-up
        i. 1st phone call date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
        ii. 2nd phone call date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
        iii. 3rd phone call date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
        iv. Certified letter date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
        v. Additional efforts: _____
    e. ☐ Revision/Removal of the tibial baseplate
    f. ☐ Subject withdrawal
    g. ☐ Surgery not performed
    h. ☐ Other (specify): _____

3. Was study device in place at last contact (Please choose one):
    a. ☐ Yes
    b. ☐ No

Comments:
Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐
Patient Initials (if there's no middle initial please use a "-") ☐☐☐
Event Onset Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
Operative Side ☐Left ☐Right

Adverse Event

1. When did event occur (Please choose one):
   a. ☐ Pre-op
   b. ☐ Peri-op
   c. ☐ Post-op

2. Adverse event (Please choose one):
   a. ☐ Arthrofibrosis
   b. ☐ Deep joint infection
   c. ☐ Excessive knee pain
   d. ☐ Femoral fracture
   e. ☐ Loosening femoral component
   f. ☐ Loosening patella component
   g. ☐ Loosening tibial component
   h. ☐ Myositis ossificans
   i. ☐ Patella component dislocation
   j. ☐ Patella fracture
   k. ☐ Patella subluxation
   l. ☐ Patella tendon rupture
   m. ☐ Peroneal nerve palsy
   n. ☐ Prosthesis fracture / femoral component
   o. ☐ Prosthesis fracture / patella component
   p. ☐ Prosthesis fracture / tibial component
   q. ☐ Prosthesis fracture / tibial insert
   r. ☐ Reflex Sympathetic Dystrophy (RSD)
   s. ☐ Soft tissue trauma
   t. ☐ Superficial wound infection
   u. ☐ Supracondylar fracture
   v. ☐ Tibial component subsidence
   w. ☐ Tibial fracture
   x. ☐ Wound hematoma
   y. ☐ Wound related (specify): _____
   z. ☐ Operative site other (specify): _____
   aa. ☐ Bronchopulmonary (event description): _____
   bb. ☐ Carcinoma (event description): _____
   cc. ☐ Cardiovascular (event description): _____
   dd. ☐ Dermatological (event description): _____
   ee. ☐ Gastrointestinal (event description): _____
   ff. ☐ Genitourinary (event description): _____
   gg. ☐ Neurosensory (event description): _____
   hh. ☐ Pulmonary embolism
   ii. ☐ Thrombophlebitis
   jj. ☐ Trauma (event description): _____
   kk. ☐ Systemic other (event description): _____

3. Describe the event circumstances: _____

4. Device related (**for Yes & uncertain a PER must be filed and Stryker must be contacted within 24hrs**)
   a. ☐ Yes
   b. ☐ No
   c. ☐ Uncertain

5. Seriousness
    a. ☐ Resulted in inpatient hospitalization
    b. ☐ Resulted in prolonged existing hospitalization
    c. ☐ Resulted in persistent or significant disability/incapacity
    d. ☐ Resulted in permanent impairment of a body function or permanent damage to a body structure
    e. ☐ Necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure
    f. ☐ Was a life threatening situation
    g. ☐ Resulted in subject death
    h. ☐ None

6. Date AE became serious. If serious date is same as the onset date, enter the onset date:
☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Treatments

1. ☐ None

2. Revisions/Removals:
    a. ☐ Femoral component ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    b. ☐ Tibial baseplate (complete termination form) ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    c. ☐ Tibial insert ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    d. ☐ Patellar component ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

3. Reoperations
    a. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    b. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    c. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

4. Other treatment:
    a. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    b. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    c. Details/Description ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

5. Resolution of event:
6. Reoperations
    a. Unresolved as of ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
    b. Resolved as of ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Comments:
Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐

Patient Initials (if there's no middle initial please use a "-") ☐☐☐

Visit Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Operative Side ☐Left ☐Right

Demographics

Subject Completed Section:

1. Education Level (Please choose one):
   a. ☐ Less than high school
   b. ☐ High school diploma
   c. ☐ Greater than high school
   d. ☐ Decline to answer

2. Employment Status (Please choose one):
   a. ☐ Working
   b. ☐ Not working
   c. ☐Decline to answer

3. Annual household income (Please choose one):
   a. ☐ > $24,999
   b. ☐ $25,000-$49,999
   c. ☐ $50,000-$74,999
   d. ☐ $75,000-$99,999
   e. ☐ $100,000-$149,999
   f. ☐ > $150,000
   g. ☐ Decline to answer

4. Ethnicity (Please choose one):
   a. ☐ Hispanic or Latino origin
   b. ☐ Not Hispanic or Latino origin
   c. ☐ Decline to answer

5. Race (Please select all that apply):
   a. ☐ American Indian or Alaskan Native
   b. ☐ Asian
   c. ☐ Black or African
   d. ☐ Native Hawaiian or other Pacific Islander
   e. ☐ White
   f. ☐ Decline to answer

6. Cigarette Use (Please choose one):
   a. ☐ Non-smoker
   b. ☐ Current cigarette smoker
      i. *If current cigarette smoker specify number of packs/day and number of years.*
   c. ☐ Ex-cigarette smoker
      i. *If former cigarette smoker specify number of packs/day and number of years and date stopped.*
   d. ☐ Decline to answer

   #Packs/day: ☐☐ #Years: ☐☐ Date stopped: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

7. Alcohol Use:
   a. ☐ Have never used alcohol

b. ☐ Have not had alcohol in the last year
c. ☐ Less than 3 drinks a week
d. ☐ 3 – 7 drinks a week
e. ☐ 8 – 14 drinks a week
f. ☐ 15+ drinks a week
g. ☐ Decline to answer

Demographics

Site Completed Section:

1. Date of birth: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

2. Gender (Please choose one):
   a. ☐ Male
   b. ☐ Female

3. Select unit of measure:
   a. ☐ US/English
   b. ☐ Metric

4. Height: ☐☐☐ cm/in
5. Weight: ☐☐☐ lbs/kg
   a. BMI ☐☐☐

6. Primary orthopedic diagnosis (Please choose one):
   a. ☐ Osteoarthritis
   b. ☐ Traumatic arthritis
   c. ☐ Avascular necrosis
   d. ☐ Other (specify): _____

Comorbidity Component:

Does the patient have any of the following conditions (Please check all that apply):

☐ None
☐ 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

Concurrent Medical Conditions (Please check all that apply):s

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

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐

Patient Initials (if there's no middle initial please use a "-") ☐☐☐

Visit Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Operative Side ☐Left ☐Right

Follow-up Questionnaire

1. Questionnaire completed by (please choose one)?:
    a. ☐ Office/clinic visit
    b. ☐ Mail
    c. ☐ Phone

2. Do you have any pain in your knee that has the study knee replacement(Please choose one)?:
    a. ☐ Yes
        i. If yes please specify:_____
    b. ☐ No
    c. Subject comments:_____
    d. Coordinator comments:_____

3. Are you satisfied with the results of your study knee replacement(Please choose one)?:
    a. ☐ Yes
        i. If yes please specify:_____
    b. ☐ No
    c. Subject comments:_____
    d. Coordinator comments:_____

4. Have you had any surgery on your study knee since your last study required visit/contact(Please choose one)?:
    a. ☐ Yes
        i. If yes please check all that answer the following
            1. Is your tibial component of your study knee still implanted(Please choose one)?:
                a. ☐ Yes
                b. ☐ No
            2. Is your patella component of your study knee still implanted (Please choose one)?:
                a. ☐ Yes
                b. ☐ No
    b. Subject comments:_____
    c. Coordinator comments:_____

5. Height: ☐☐☐ cm/in
    a. ☐ Decline to answer

6. Weight: ☐☐☐ lbs/kg
    a. ☐ Decline to answer

7. BMI ☐☐☐

Comments:

Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐

Patient Initials (if there's no middle initial please use a "-") ☐☐☐

Visit Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Operative Side ☐Left ☐Right

Inclusion/Exclusion Form

Inclusion Criteria

Yes/No

1. ☐☐ Patient has signed an IRB/EC approved; study specific Informed Patient Consent Form.
   a. Informed Consent Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
2. ☐☐ Patient is a male or non-pregnant female age 18 – 75 years at time of study device implantation.
3. ☐☐ Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
4. ☐☐ Patient is a candidate for primary cementless total knee replacement, including a resurfaced patella.
5. ☐☐ Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

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

Exclusion Criteria

Yes/No

1. ☐☐ Patient has a Body Mass Index (BMI) > 40.
2. ☐☐ Patient has a diagnosis of avascular necrosis or inflammatory arthritis.
3. ☐☐ Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation.
4. ☐☐ Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device.
5. ☐☐ Subject is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's Disease) leading to progressive bone deterioration.
6. ☐☐ Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days).
7. ☐☐ Patient is diagnosed with lumbar radicular pain.
8. ☐☐ Patient has a known sensitivity to device materials.
9. ☐☐ Patient is a prisoner.

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

Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Oxford Knee Score (OKS)

English version for the United States

PROBLEMS WITH YOUR KNEE

Check (✓) one box for every question.

1. During the past 4 weeks...

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transportation because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

For how long have you been able to walk before pain from your knee becomes **severe**? (with or without a cane)

No pain/more than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all/severe pain when walking
☐	☐	☐	☐	☐

5. During the past 4 weeks...

After a meal (sitting at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
☐	☐	☐	☐	☐

6. During the past 4 weeks...

Have you been limping when walking because of your knee?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

7. During the past 4 weeks...

Could you kneel down and get up again afterwards?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks...

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

9. During the past 4 weeks...

How much has pain from your knee interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

10. During the past 4 weeks...

Have you felt that your knee might suddenly "give out" or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

11. During the past 4 weeks...

Could you do the grocery shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

12. During the past 4 weeks...

Could you walk down one flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

Finally, please check that you have answered each question.

Thank you very much.

Appendix 2

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KNEE SOCIETY SCORE: POST-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex ○ Male ○ Female

6- Side of this (surgically treated) knee ○ Left ○ Right
If both knees have been operated on, please use a different form for each knee

7- Ethnicity

○ Native Hawaiian or other Pacific Islander ○ American Indian or Alaska Native ○ Hispanic or Latino

○ Arab or Middle Eastern ○ African American or Black ○ Asian ○ White

8- Please indicate date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Was this a primary or revision knee replacement?

○ Primary ○ Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

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OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

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SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

○ Always (5 pts) ○ Sometimes (3 pts) ○ Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

Maximum total points (40 points)

9727547315

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points)

0511547317

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FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? (0 points)

○ Yes ○ No

2 - If no, which of the following aid(s) do you use? (-10 points)

○ wheelchair (-10 pts) ○ walker (-8 pts) ○ crutches (-8 pts) ○ two canes (-6 pts)

○ one crutch (-4 pts) ○ one cane (-4 pts) ○ knee sleeve / brace (-2 pts)

○ other

3 - Do you use these aid(s) because of your knees? (0 points)

○ Yes ○ No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? (15 points)

○ cannot stand (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? (15 points)

○ cannot walk (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

Maximum points (30 points)

5272547316

Page 6/7

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	○	○	○	○	○	○	○	
2 - Turning or pivoting on your leg	○	○	○	○	○	○	○	
3 - Climbing up or down a flight of stairs	○	○	○	○	○	○	○	
4 - Getting up from a low couch or a chair without arms	○	○	○	○	○	○	○	
5 - Getting into or out of a car	○	○	○	○	○	○	○	
6 - Moving laterally (stepping to the side)	○	○	○	○	○	○	○	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	○	○	○	○	○	○	○	
2 - Carrying a shopping bag for a block	○	○	○	○	○	○	○	
3 - Squatting	○	○	○	○	○	○	○	
4 - Kneeling	○	○	○	○	○	○	○	
5 - Running	○	○	○	○	○	○	○	

Maximum points (25 points)

4511547311

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DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ 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 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐

Patient Initials (if there's no middle initial please use a "-") ☐☐☐

Visit Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Operative Side ☐Left ☐Right

Post-op Functional Evaluation

1. Have there been any protocol defined Adverse Events since the last visit? Used (Please choose one):
    a. ☐ Yes
        i. If yes complete AE form for each event.
    b. ☐ No

[redacted]

Use this section to report medical events other than protocol defined adverse events.

2. Has the subject seen a doctor for any medical event since the last visit?:
    a. ☐ Yes
        i. If yes please specify_____
    b. ☐ No

3. Has the subject been hospitalized for any elective surgery since the last visit?:
    a. ☐ Yes
        i. If yes please check all that apply
        ii. ☐ Contralateral knee
        iii. ☐ Contralateral hip
        iv. ☐ Ipsilateral hip
        v. ☐ Contralateral shoulder
        vi. ☐ Ipsilateral shoulder
        vii. ☐ Cataract
        viii. ☐ Other (specify):_____
    b. ☐ No
    c. Elective hospitalization details:_____

4. Is anything currently affecting the subject's function?:
    a. ☐ Yes
        i. If yes please specify_____
    b. ☐ No

[redacted]

Comments:

Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Appendix 1

3563569401 Page 1/7

KNEE SOCIETY SCORE: PRE-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex ○ Male ○ Female

6- Side of this (symptomatic) knee ○ Left ○ Right

If both knees will be operated on, please use a different form for each knee

7- Ethnicity

○ Native Hawaiian or other Pacific Islander ○ American Indian or Alaska Native ○ Hispanic or Latino

○ Arab or Middle Eastern ○ African American or Black ○ Asian ○ White

8- Please indicate the expected date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Will this be a primary or revision knee replacement?

○ Primary ○ Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

4973569407

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

8099569400

Page 3/7

SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

○ Always (5 pts) ○ Sometimes (3 pts) ○ Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

Maximum total points (40 points)

9296569400

PATIENT EXPECTATIONS (To be completed by patient)

What do you expect to accomplish with your knee replacement:

1- Do you expect your knee joint replacement surgery will relieve your knee pain? **(5 points)**

○ no, not at all (1 pt)
○ yes, a little bit (2 pts)
○ yes, somewhat (3 pts)
○ yes, a moderate amount (4 pts)
○ yes, a lot (5 pts)

2- Do you expect your surgery will help you carry out your normal activities of daily living? **(5 points)**

○ no, not at all (1 pt)
○ yes, a little bit (2 pts)
○ yes, somewhat (3 pts)
○ yes, a moderate amount (4 pts)
○ yes, a lot (5 pts)

3- Do you expect you surgery will help you perform leisure, recreational or sports activities? **(5 points)**

○ no, not at all (1 pt)
○ yes, a little bit (2 pts)
○ yes, somewhat (3 pts)
○ yes, a moderate amount (4 pts)
○ yes, a lot (5 pts)

Maximum total points (15 points)

5216569408

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FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? (0 points)

○ Yes ○ No

2 - If no, which of the following aid(s) do you use? (-10 points)

○ wheelchair (-10 pts) ○ walker (-8 pts) ○ crutches (-8 pts) ○ two canes (-6 pts)

○ one crutch (-4 pts) ○ one cane (-4 pts) ○ knee sleeve / brace (-2 pts)

○ other

3 - Do you use these aid(s) because of your knees? (0 points)

○ Yes ○ No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? (15 points)

○ cannot stand (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? (15 points)

○ cannot walk (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

Maximum points (30 points)

0541569404

Page 6/7

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	○	○	○	○	○	○	○	
2 - Turning or pivoting on your leg	○	○	○	○	○	○	○	
3 - Climbing up or down a flight of stairs	○	○	○	○	○	○	○	
4 - Getting up from a low couch or a chair without arms	○	○	○	○	○	○	○	
5 - Getting into or out of a car	○	○	○	○	○	○	○	
6 - Moving laterally (stepping to the side)	○	○	○	○	○	○	○	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	○	○	○	○	○	○	○	
2 - Carrying a shopping bag for a block	○	○	○	○	○	○	○	
3 - Squatting	○	○	○	○	○	○	○	
4 - Kneeling	○	○	○	○	○	○	○	
5 - Running	○	○	○	○	○	○	○	

Maximum points (25 points)

7470569402

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DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ 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 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)

Your Health and Well-Being

This survey asks for your views about your health. This information will help 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 an ☒ in the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> 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	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

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>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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 with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Stryker®

Triathlon Tritanium Knee Study

Patient ID: 74 - ☐☐ - ☐☐☐☐
Patient Initials (if there's no middle initial please use a "-") ☐☐☐
Visit Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY
Operative Side ☐Left ☐Right

Surgical Details

1. Type of Anesthesia Used (Please check all that apply):
    a. ☐ General
    b. ☐ Spinal
    c. ☐ Epidural
    d. ☐ Femoral Block
    e. ☐ Not recorded

2. ASA Score (Please choose one):
    a. ☐ ASA 1
    b. ☐ ASA 2
    c. ☐ ASA 3
    d. ☐ ASA 4
    e. ☐ ASA 5
    f. ☐ Not recorded

3. Surgical Approach (Please choose one):
    a. ☐ Medial Parapatellar
    b. ☐ Lateral Parapatellar
    c. ☐ Sub Vastus
    d. ☐ Mid Vastus

4. Navigation Used (Please choose one):
    a. ☐ Yes
    b. ☐ No

5. Femoral Instrumentation Referencing (Please choose one):
    a. ☐ Anterior Referencing
    b. ☐ Posterior Referencing

6. Femoral Instrumentation Alignment (Please choose one):
    a. ☐ Internal Alignment
    b. ☐ External Alignment
    c. ☐ Not recorded

7. Tibial Instrumentation Referencing (Please choose one):
    a. ☐ Internal Alignment
    b. ☐ External Alignment
    c. ☐ Not recorded

8. Bone removed (Please complete for each):
    a. Distal Femur: ☐☐☐mm
        i. ☐ Not recorded
    b. Proximal Femur: ☐☐☐mm
        i. ☐ Not recorded

9. Estimated blood loss
    a. ☐ ☐☐☐cc's
        i. ☐ Not recorded

10. Units of blood transfused
    a. ☐ ☐☐☐cc's
        i. ☐ Not recorded

11. Skin to skin time
    a. ☐ ☐☐minutes
        i. ☐ Not recorded

12. Tourniquet time
    a. ☐ ☐☐minutes
        i. ☐ Not recorded

13. Soft tissue released (Please check all that apply):

☐None
☐ Illiotibial tract
☐ Parapatellar
☐ Popliteus tendon
☐ Poster-lateral capsule
☐ Lateral collateral ligament
☐ Bicep femoris tendon
☐ Peptic ulcer disease
☐ Lateral head of gastrocnemius
☐ Medial collateral ligament
☐ Lateral retinacular
☐ Posterior cruciate ligament
☐ Posterior medial capsule
☐ Other (specify)
☐ Not recorded

14. Intraoperative complication (Please choose one):
    a. ☐ Yes
    b. ☐ No

15. Antibiotic prophylaxis used (Please choose one):
    a. ☐ Yes
        i. If yes please specify type_____
    b. ☐ No

16. Blood loss prophylaxis used (Please choose one):
    a. ☐ Yes
        i. If yes please specify type_____
    b. ☐ No

17. How satisfied are you with the initial fixation? (Please choose one):
    a. ☐ Extremely
    b. ☐ Quite a bit
    c. ☐ Moderately
    d. ☐ A little bit
    e. ☐ Not at all

18. Discharge Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

19. Discharged to (Please choose one):
    a. ☐ Skilled nursing facility
    b. ☐ Chronic care center
    c. ☐ Rehabilitation unit
    d. ☐ Home
    e. ☐ Other (specify)
    f. ☐ Not recorded

20. Post-op plan (Please choose one):
    a. ☐ Full weight bearing
    b. ☐ Partial weight bearing
    c. ☐ Not recorded

Component Listing:

Femoral Component: Reference# and Lot#, Tibial Component/ Metal Tray: Reference# and Lot#, Tibial Insert/ UHMWPE Bearing: Reference# and Lot# and Patellar Component: Reference# and Lot#

Comments:
Investigator signature:_____ Date: ☐☐-☐☐☐-☐☐☐☐ DD-MMM-YYYY

Appendix G

Product Labeling

stryker
Howmedica
OSTEONICS

Howmedica Osteonics TRIATHLON TRITANIUM TOTAL KNEE IFU

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

EC REP

Stryker France
ZAC Satolas Green Pusignan
Av de Satolas Green
69881 MEYZIEU Cedex
FRANCE

Telephone #: +1 201-831-5000

CE 0086

QIN 4419 Rev. A

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

Labeling Symbols

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

English

HOWMEDICA OSTEONICS TRIATHLON TRITANIUM TOTAL KNEE IFU

Description

Howmedica Osteonics Corp.'s total knee systems include the Triathlon Tritanium Baseplate which is designed to be used with the Triathlon Primary Knee system femoral components, tibial inserts, and patellar components for total reconstructive replacement of the knee joint. The characteristics specific to each device are detailed on the product label. The Triathlon Tritanium Baseplate is indicated for both cementless and cemented applications.

Femoral Components: The Triathlon Tritanium Baseplate is compatible with the Triathlon cruciate retaining (CR), and cruciate sacrificing (posteriorly stabilized – PS) designs.

Tibial Components: The Triathlon Tritanium Baseplate is compatible with Triathlon tibial inserts in a cruciate retaining (CR), posterior stabilized (PS), and condylar stabilizing (CS) designs. Tibial inserts are available in a range of thicknesses and in various degrees of constraint.

Note: The Triathlon Tritanium Baseplate is packaged together with an Impactor Pad. The Impactor Pad is to be used during the tibial baseplate impaction step only and is to be discarded once impaction has completed. The Impactor Pad is not for implantation.

Patellar Components: Patellar resurfacing components are available in all-plastic symmetric and -asymmetric and metal-backed designs. Use of a patellar component is optional. The Triathlon Tritanium Baseplate is compatible with all Triathlon patellar components.

Materials

• ASTM F-75 cobalt chromium alloy	Femoral components
• ASTM F-90 cobalt chromium alloy	Locking wire for tibial inserts
• ASTM F-1537 cobalt chromium alloy	Femoral pegs
• ASTM F-136 titanium alloy	Tibial components
• ASTM F-67 CP Titanium	Tibial components
• ASTM F-1185 calcium phosphate	Femoral components, patellar components
• ASTM F-648 Ultra high molecular weight polyethylene	Tibial bearing inserts, patellar components

Indications

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 Baseplate is indicated for both cementless and cemented use.

Additional Indications for Posterior Stabilized (PS) 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.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Precautions

- Surgeons must advise patients of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Surgeons should caution patients to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- Surgeons should warn patients of potential adverse effects, including the finite service life of the device and the need for post operative protection of the implant. The surgeon should warn patients that the device does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint and that the implant can break or become damaged as a result of strenuous activity or trauma.
- Appropriate selection, placement and fixation of the total knee components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

Utilization and Implantation

- Use the recommended trial components for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Care should be taken to remove bone chips, bone cement fragments and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surfaces of the implant.
- Howmedica Osteonics Corp. 's Surgical Protocols provide additional procedural information.
- Consult the product label for specific product compatibility. Generally, the following applies:
  - Use PS femorals only with PS Tibial Bearings
  - Use CR femorals only with CR Tibial Bearings
  - Use either PS or CR femorals with CS Tibial Bearings

Information for patients

- The surgeon must advise the patient of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

- The surgeon should caution the patient to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- The surgeon should warn the patient of surgical risks and possible adverse effects. The surgeon should warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma and that the device has a finite service life and may need to be replaced in the future.
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Warnings

- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Do not implant the Impactor Pad. The Impactor Pad is to be used only during the tibial impaction step. Remove and discard immediately following the impaction process.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- The metal retaining wire on the insert should not be handled or removed, as it is critical to the security of the assembly. Discard any tibial bearing insert if the metal retaining wire appears damaged or mishandled. Tampering with this assembly can result in improper function of the retaining mechanism.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Except where noted, Howmedica Osteonics Corp. strongly advises against the use of another manufacturer's total knee component with any of Howmedica Osteonics' total knee components. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Howmedica Osteonics Corp. strongly advises against the use of another manufacturer's bone screws with any of Howmedica Osteonics' total knee components, due to variations which exist between screw head and screw seat configurations.
- Intentional removal of a total knee component can be accomplished by careful use of cutting burs, thin and narrow osteotomes and cautious extraction forces.
- Intentional removal of the plastic tibial insert after its assembly into the metal baseplate results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial baseplate during insert removal.
- Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**

Adverse Effects

- While the expected life of total knee replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated *in vivo*, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Surgeons should counsel patients against having unrealistic expectations about the lifetime of the device.
- Dislocation of the femoral, tibial, or patellar prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

- Fatigue fracture of total knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint and/or amputation of the limb.
- Soft tissue imbalance and/or laxity has been related to component malalignment, which may result in early wear and/or failure of the implant.
- With all implant 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 cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
- It is known that very small particles from metal and polyethylene components can be shed from the component during normal use and over time. Although most of this debris stays in the relevant joint (e. g. contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can possibly travel or migrate outside of the joint to different parts of the body. Currently, there are unanswered questions about debris and microscopic particles that can be generated from these components. It has been shown that microscopic debris particles can be disseminated (migrate) throughout the body and on occasion have been described as accumulating in lymph nodes and other parts of the body. Although to date no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. Given the insufficient time period during which patients with these devices have been followed and the fact that these devices are currently being used in younger patients and remain in the body for increasingly longer periods of time, it should be said that the long-term effects, if any, from these particles, is unknown. The long-term effects that have been theorized include:
  - **Cancer:** There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
  - **Lymphadenopathy and Accumulation in Other Tissues/Organs:** There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease processes have been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
  - **Systemic Disease:** There has been some speculation that there could be an association between migration of debris and as yet unspecified systemic effects. It is possible that some long-term effects maybe demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long term effect.

Interaction with Magnetic Resonance Imaging

The Triathlon Knee System has not been evaluated for safety and compatibility in the MR environment. The Triathlon Knee System has not been tested for heating or migration in the MR environment.

Sterilization

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

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

WARNING: Components labeled for "Cemented Use Only" are to be implanted only with bone cement.

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

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

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

Français

HOWMEDICA OSTEONICS MODE D'EMPLOI POUR PROTHESE TOTALE DE GENOU TRIATHLON TRITANIUM

Description

Les prothèses totales de genou de Howmedica Osteonics Corp. comprennent le plateau Triathlon Tritanium conçu pour être utilisé avec les composants fémoraux du système primaire du genou Triathlon, les inserts tibiaux et les composants rotuliens pour une arthroplastie totale du genou. Les caractéristiques spécifiques à chaque dispositif sont détaillées sur l'étiquette du produit. Le plateau Triathlon Tritanium est indiqué pour les applications cimentées et non cimentées.

Composants fémoraux : Le plateau Triathlon Tritanium est compatible avec les conceptions Triathlon avec préservation des ligaments croisés (CR) et la non conservation des ligaments croisés (postéro-stabilisés - PS).

Composants tibiaux : Le plateau Triathlon Tritanium est compatible avec les conceptions d'inserts tibiaux Triathlon avec préservation des ligaments croisés (CR), postéro-stabilisés (PS) et stabilisation condylienne (CS). Les inserts tibiaux sont disponibles dans une gamme d'épaisseurs et des degrés variés de contraintes.

Remarque : Le conditionnement du plateau Triathlon Tritanium est accompagné d'un coussin pour impacteur. Le coussin pour impacteur doit être utilisé pendant la phase d'impaction du plateau tibial uniquement et doit être éliminé une fois l'impaction terminée. Le coussin pour impacteur n'est pas destiné à l'implantation.

Composants rotuliens : Les composants de resurfaçage rotuliens sont disponibles dans des conceptions symétriques et asymétriques tout en plastique et avec support en métal. L'utilisation d'un composant rotulien est optionnelle. Le plateau Triathlon Tritanium est compatible avec tous les composants rotuliens Triathlon.

Matériaux

• Alliage cobalt chrome ASTM F-75	Composants fémoraux
• Alliage cobalt chrome ASTM F-90	Fil de retenue pour inserts tibiaux
• Alliage cobalt chrome ASTM F-1537	Chevilles fémorales
• Alliage de titane ASTM F-136	Composants tibiaux
• Titane CP ASTM F-67	Composants tibiaux
• Phosphate de calcium ASTM F-1185	Composants fémoraux, composants rotuliens
• Polyéthylène de masse moléculaire très élevée ASTM F-648	Inserts d'appui tibiaux, composants rotuliens

Indications

Indications pour arthroplastie générale totale du genou :

- Maladies articulaires douloureuses du genou entraînant l'invalidité suite à : une maladie articulaire dégénérative non inflammatoire (y compris l'arthrose, l'arthrite traumatique ou la nécrose avasculaire), la polyarthrite rhumatoïde ou l'arthrite post-traumatique.
- Perte post-traumatique de la configuration et de la fonction de l'articulation du genou.
- Déformation modérée en varus, valgus ou de flexion permettant aux structures ligamenteuses de récupérer une fonction et stabilité adéquates.
- Révision d'un échec de prothèse de genou ou autre intervention antérieure.
- Fracture du fémur distal et/ou du tibia proximal ne pouvant pas être stabilisée par des techniques de gestion des fractures standards.

Le plateau Triathlon Tritanium est indiqué pour des applications cimentées et non cimentées.

Indications supplémentaires pour les composants postéro-stabilisés:

- Instabilité ligamentaire exigeant des géométries de surface d'appui d'implant à contrainte accrue.
- Ligament croisé postérieur absent ou déficient.
- Instabilité antéro-postérieure sévère de l'articulation du genou.

Contre-indications

- Toute infection active ou latente dans ou autour de l'articulation du genou.
- Foyer distant d'infection pouvant entraîner une propagation hématogène au site de l'implant.
- Tout trouble mental ou neuromusculaire constituant un risque inacceptable d'instabilité de la prothèse, échec de fixation de la prothèse ou complications du traitement postopératoire.
- Masse osseuse compromise par la maladie, une infection ou une implantation précédente qui ne peut pas fournir un support adéquat et/ou une fixation à la prothèse.
- Immaturité du squelette.
- Grave instabilité de l'articulation du genou suite à l'absence d'intégrité ou de fonction des ligaments collatéraux.
- Obésité. Un patient en surpoids ou obèse peut soumettre la prothèse à des sollicitations susceptibles de compromettre la fixation du dispositif ou le dispositif même.

Précautions

- Le chirurgien doit informer le patient des limitations de la reconstruction et de la nécessité de protéger l'implant de l'appui du poids total jusqu'à ce que la fixation appropriée et la consolidation se soient produites. Une activité excessive et un traumatisme de l'articulation prothétique peuvent entraîner l'échec de la reconstruction par descellement, fracture ou/et usure des implants prothétiques. Le descellement de composants peut entraîner une augmentation de la production de particules d'usure et endommager l'os, ce qui rend une éventuelle reprise plus difficile.
- Le chirurgien doit conseiller au patient de limiter ses activités, de ne pas soumettre la prothèse à des sollicitations excessives, et de respecter les instructions du médecin relatives aux soins et traitements postopératoires.
- Le chirurgien doit aviser le patient d'effets indésirables potentiels, y compris de la durée de vie utile limité du dispositif et le besoin d'une protection post-opératoire de l'implant. Le chirurgien doit aviser le patient qu'une prothèse ne jouit pas de la souplesse, de la solidité, de la fiabilité et de la durabilité d'une articulation saine et normale, qu'un implant peut se rompre ou être endommagé par des activités trop exigeantes ou par un traumatisme.
- Le choix, le placement et la fixation appropriés des composants de prothèse totale du genou sont des facteurs essentiels affectant la durée de vie utile de l'implant. Comme dans le cas de toutes les prothèses, la durabilité de ces composants est affectée par de nombreux facteurs biologiques, biomécaniques et autres facteurs extrinsèques qui limitent leur durée de vie utile. Ainsi, une adhérence stricte aux indications, contre-indications, précautions et mises en garde de ce produit est essentielle pour maximiser la durée de vie utile.

Utilisation et implantation

- Utiliser les composants d'essai recommandés pour déterminer la taille, pour les essais de réduction et pour l'évaluation de l'amplitude des mouvements préservant ainsi l'intégrité des implants et leur conditionnement stérile.
- Des modèles radiographiques sont disponibles pour aider à la prédiction peropératoire de la taille et du style de composant.
- Prendre soin de retirer les éclats d'os, fragments de ciment osseux et débris métalliques du site de l'implant pour réduire le risque d'une usure accélérée des surfaces d'articulation de l'implant engendrée par les débris.

- Les protocoles chirurgicaux de Howmedica Osteonics Corp. donnent des informations procédurales supplémentaires.
- Consulter l'étiquette du produit pour des informations spécifiques concernant la compatibilité du produit. En général, les règles suivantes s'appliquent :
  - Utiliser les composants fémoraux PS uniquement avec des appuis tibiaux PS.
  - Utiliser les composants fémoraux CR uniquement avec des appuis tibiaux CR.
  - Utiliser les composants fémoraux PS ou CR uniquement avec des appuis tibiaux CS.

Informations destinées au patient

- Le chirurgien doit informer le patient des limitations de la reconstruction et de la nécessité de protéger l'implant de l'appui du poids total jusqu'à ce que la fixation appropriée et la consolidation se soient produites. Une activité excessive et un traumatisme de l'articulation prothétique peuvent entraîner l'échec de la reconstruction par descellement, fracture ou/et usure des implants prothétiques. Le descellement de composants peut entraîner une augmentation de la production de particules d'usure et endommager l'os, ce qui rend une éventuelle reprise plus difficile.
- Le chirurgien doit conseiller au patient de limiter ses activités, de ne pas soumettre la prothèse à des sollicitations excessives, et de respecter les instructions du médecin relatives aux soins et traitements postopératoires.
- Le chirurgien doit avertir le patient des risques chirurgicaux et des effets indésirables possibles. Le chirurgien doit expliquer au patient qu'une prothèse ne jouit pas de la souplesse, de la solidité, de la fiabilité et de la durabilité d'une articulation saine et normale, qu'un implant peut se rompre ou être endommagé par des activités trop exigeantes ou par un traumatisme, et qu'une prothèse a une durée de vie utile limitée et qu'il peut s'avérer nécessaire de la remplacer dans l'avenir.
- Une bactériémie passagère peut survenir dans la vie quotidienne normale. Des soins dentaires, des examens endoscopiques et d'autres interventions chirurgicales mineures peuvent également être associés à une bactériémie passagère. En prévention d'une infection au niveau du site d'implantation il peut être conseillé d'administrer une prophylaxie antibiotique avant et après de telles interventions.

Mises en garde

- Éliminer tous les implants endommagés ou défectueux.
- Ne jamais réutiliser un implant, même s'il semble en bon état.
- Ne pas implanter le coussin pour impacteur. Le coussin pour impacteur ne doit servir que pendant la phase d'impaction de l'implant. Retirer et éliminer immédiatement suite au processus d'impaction.
- Éviter tout contact entre les surfaces d'appui polies et les surfaces dures ou abrasives.
- Les surfaces d'appui doivent toujours être propres et libres de débris avant l'assemblage.
- La résistance à la fatigue d'un implant qui a été cintré ou courbé peut être réduite, avec risque de défaillance sous contrainte.
- Le fil de retenue métallique dont est muni l'insert ne doit jamais être manipulé ou retiré, car il joue un rôle critique pour la sécurité de l'assemblage. Éliminer tout insert d'appui tibial si le fil de retenue métallique semble être endommagé ou défectueux. Toute altération de cet assemblage peut se traduire par un mauvais fonctionnement du mécanisme de fixation.
- Veiller à ne pas couper les gants chirurgicaux lors de la manipulation d'un dispositif orthopédique tranchant.
- Sauf spécification contraire, Howmedica Osteonics Corp. déconseille vivement l'utilisation d'un composant de prothèse totale du genou d'un autre fabricant avec un composant de prothèse totale du genou de Howmedica Osteonics. Une telle utilisation dégage Howmedica Osteonics Corp. de toute responsabilité relative aux performances de l'implant mixte qui en résulte.
- Howmedica Osteonics Corp. déconseille vivement l'utilisation de vis osseuses d'un autre fabricant avec un composant de prothèse totale du genou Howmedica Osteonics à cause de différences de configuration des têtes de vis et des surfaces d'appui des vis.

- La résection d'un composant de prothèse totale du genou peut être réalisée par l'utilisation délicate de fraises coupantes, d'ostéotomes fins et étroits et de la force lors de l'extraction.
- La résection de l'insert tibial en plastique après son assemblage dans le plateau métallique entraîne la destruction de cet insert. Veiller à ne pas entailler ni abîmer la surface du plateau tibial lors de la résection de l'insert.
- Tout produit présentant une brèche dans le conditionnement stérile doit être renvoyé au fournisseur. **Ne pas restériliser.**

Effets indésirables

- Bien que la durée prévue des composants de remplacement de prothèse totale du genou soit difficile à estimer, elle est limitée. Ces composants sont constitués de matières étrangères implantées dans l'organisme dans le but de restaurer une mobilité ou de réduire la douleur. Cependant, compte tenu des nombreux facteurs biologiques, mécaniques et physicochimiques qui peuvent affecter ces dispositifs mais qui ne peuvent être évalués *in vivo*, on ne peut pas s'attendre à ce que les composants résistent indéfiniment au niveau d'activité et aux sollicitations d'os sains normaux. Le chirurgien doit aviser le patient de ne pas avoir des attentes non réalistes concernant la durée de vie utile du dispositif.
- Une luxation de prothèse fémorale, tibiale ou rotulienne peut se produire suite à des activités inappropriées du patient, un traumatisme ou autres considérations biomécaniques.
- Il y a un risque de descellement des composants de la prothèse totale du genou. Le descellement mécanique précoce peut résulter d'une fixation initiale inadéquate, une infection latente, un chargement prématuré de la prothèse, un mauvais alignement des composants ou un traumatisme. Le descellement tardif peut résulter d'un traumatisme, d'une infection, de complications biologiques y compris l'ostéolyse, ou de problèmes mécaniques, avec comme conséquence la possibilité d'érosion de l'os et/ou la douleur.
- Une fracture de fatigue de composants de prothèse totale du genou, notamment de composants tibiaux, fémoraux et rotuliens, s'est produite dans un pourcentage minime de cas. Une fracture de composant du genou peut être provoquée par un soutien insuffisant par l'os sous-jacent ou une mauvaise fixation du composant.
- Il existe également des risques de neuropathies périphériques, lésions nerveuses, problèmes du système circulatoire et la formation d'os hétérotopiques.
- Toute implantation de prothèse articulaire totale peut être associée à des complications graves. Ces complications comprennent notamment : des troubles urogénitaux, troubles gastro-intestinaux, troubles vasculaires y compris les thromboses, troubles bronchopulmonaires y compris les embolies, les infarctus du myocarde ou le décès.
- L'usure de composants en polyéthylène est possible et des publications l'ont attribuée à une résorption osseuse, à un descellement ou à une infection.
- Des réactions d'intolérance au métal ont été signalées après une implantation de prothèse articulaire.
- Certains effets indésirables peuvent nécessiter la ré-opération, la reprise, l'arthrodèse de l'articulation concernée et/ou l'amputation du membre.
- Le déséquilibre des tissus mous et/ou la laxité ont été liés au mauvais alignement des composants et peuvent avoir comme résultat l'usure précoce et/ou la défaillance de l'implant.
- Après toute arthroplastie, il peut se produire une résorption osseuse progressive localisée (ostéolyse) asymptomatique autour des composants de l'implant, suite à une réaction de type corps étranger aux matières particulaires du ciment, du métal, du polyéthylène de masse moléculaire très élevée (UHMWPE) et/ou de la céramique. Ces matières particulaires sont produite par des interactions entre composants, ainsi qu'entre composants et l'os, principalement par des mécanismes d'usure par adhésion, abrasion et fatigue. Les matières particulaires peuvent être générés secondairement par usure d'un troisième corps. L'ostéolyse peut entraîner des complications ultérieures y compris le descellement, nécessitant une explantation et le remplacement de composants prothétiques.
- De très petites particules provenant de composants métalliques et en polyéthylène peuvent se détacher des composants pendant une utilisation normale au cours du temps. Bien que la plupart de ces débris particulaires restent dans l'articulation concernée (c.-à-d contenus dans le liquide synovial) ou sont

piégés dans le tissu cicatriciel environnant, certaines particules microscopiques peuvent migrer dans d'autres parties du corps. Des questions restent actuellement sans réponse en ce qui concerne les débris et particules microscopiques pouvant être produites par ces composants. Il a été démontré que des particules microscopiques peuvent migrer dans le corps et à l'occasion peuvent s'accumuler dans les ganglions lymphatiques et dans d'autres parties du corps. Bien qu'aucune complication médicale notable n'ait été signalée suite à la présence de ces particules, leur migration et/ou leur accumulation dans le corps ont été décrits dans la littérature. Étant donné que les patients munis de ces dispositifs ont été suivis pendant une période de temps insuffisante et étant donné que ces dispositifs sont actuellement utilisés chez des jeunes patients et qu'ils restent dans le corps pendant des périodes de temps de plus en plus longues, les effets de ces particules à long terme, s'il y en a, ne sont pas connus. Les effets à long terme font l'objet de théories dont :

- **Cancer :** Il n'existe actuellement aucune preuve scientifique liant les débris particulaires métalliques ou en polyéthylène an cancer. Toutefois, cette possibilité ne peut pas être écartée.
- **Lymphadénopathie et accumulations dans d'autres tissus ou organes du corps :** L'accumulation de débris particulaires dans les ganglions lymphatiques (proximaux et distaux) a été rapportée à plusieurs reprises. Bien qu'aucune complication médicale ou processus pathogénique n'ait été signalé comme faisant suite à ces accumulations, leur existence doit être reconnue pour faciliter le diagnostic et éviter la confusion avec des lésions douteuses, cancéreuses ou autres.
- **Maladie systémique :** Des hypothèses ont été émises concernant le rapport entre la migration des débris et des effets systémiques non précisés à ce jour. Il est possible que certains effets à long terme soient démontrés dans l'avenir, mais étant donné que les données scientifiques indiquant une association entre la migration des débris particulaires et les maladies systémiques sont rares, les avantages de ces dispositifs sont considérés comme l'emportant largement sur les risques potentiels de tels effets théoriques à long terme.

Interaction avec l'imagerie de résonance magnétique

Les prothèses du genou Triathlon n'ont pas été évaluées en termes de sécurité et compatibilité dans un environnement de résonance magnétique. Les prothèses du genou Triathlon n'ont pas été évaluées en termes de réchauffement ou migration dans un environnement de résonance magnétique.

Stérilisation

- Ce composant de prothèse totale du genou a été stérilisé par rayonnement gamma ou par plasma de peroxyde d'hydrogène. Se référer à l'étiquette du produit pour la méthode de stérilisation.
- Avant ouverture, vérifier l'intégrité du conditionnement de la barrière stérile de chaque produit. En cas de dommage quelconque, le produit doit être considéré comme non stérile. Des prothèses d'essai spéciales sont disponibles afin d'éviter l'ouverture du conditionnement stérile avant l'utilisation de son contenu.
- Prendre les mesures nécessaires pour éviter toute contamination du composant. En cas de contamination, le produit doit être éliminé.
- Si le conditionnement a été ouvert et le produit non utilisé, ne pas restériliser le composant qui doit être éliminé ou renvoyé au fournisseur.
- Le dispositif ne doit pas être utilisé après la date d'expiration figurant sur l'étiquette, car le conditionnement ne peut pas être validé au-delà de cette date.
- Les dispositifs à utilisation uniques ne peuvent pas être explantés et ensuite réimplantés car les forces physiques exercées par ces actions peuvent compromettre l'intégrité physique, les dimensions et/ ou la finition de la surface des dispositifs. De même, la stérilité ne peut pas être assurée pour les dispositifs réutilisés car les procédures de nettoyage et de re-stérilisation n'ont pas été vérifiées.

ATTENTION : **EN VERTU DE LA LOI FÉDÉRALE (USA) LA VENTE DE CE DISPOSITIF EST STRICTEMENT RÉSERVÉE À UN MÉDECIN OU SUR SON ORDRE.**

AVERTISSEMENT : Les composants dont l'étiquette indique « Pour utilisation cimentée uniquement » doivent être implantés uniquement à l'aide de ciment osseux.

Stryker Corporation, ses services ou autres filiales détiennent, utilisent ou ont déposé la ou les marques commerciales suivantes : Howmedica, Osteonics, Stryker, Triathlon. Toutes les autres marques commerciales ou de service appartiennent à leurs propriétaires ou détenteurs respectifs.

Se référer à l'étiquette du produit concernant l'état de marquage CE et le fabricant légal. Le marquage CE n'est valide que s'il se trouve aussi sur l'étiquette du produit.

Le tableau suivant donne une liste d'abréviations utilisées pour l'étiquetage des produits Howmedica Osteonics Corp. :

Terme	Abréviation	Terme	Abréviation
Code Alpha	ALPH CDE	Cou	NK
Angle	ANG	Décalage	OFFST
Degré	DEG or °	Diamètre externe	OD
Diamètre	DIA	Droit	RT ▶
Extra Profond	XDP	Orifices de vis	SCR HLS
Extra Large	XLGE	Côté	SDE
Extra Petit	XSM	Taille	SZE
Tête	HD	Petit	SM
Hauteur	HT	Standard	STD
Diamètre Interne	ID	Cône	TPR
Insert	INSR	Épaisseur	THKNS
Large	LGE	Type	TYP
Gauche	◀ LFT	Avec	W/
Longueur	LNTH	Sans	W/O
Médium	MED		

Deutsch

GEBRAUCHSINFORMATION TRIATHLON TRITANIUM TOTALKNIE VON HOWMEDICA OSTEONICS

Beschreibung

Die Totalkniesysteme von Howmedica Osteonics Corp. umfassen die Triathlon Tritanium Basisplatte, die zur Verwendung mit den Femurkomponenten, Tibiaeinsätzen und Patellakomponenten des Triathlon Primärkniesystems zum totalen rekonstruktiven Ersatz des Kniegelenks vorgesehen sind. Die spezifischen Eigenschaften der einzelnen Produkte sind ausführlich auf den jeweiligen Produktetiketten beschrieben. Die Triathlon Tritanium Basisplatte ist für zementfreie und zementierte Anwendungen indiziert.

Femurkomponenten: Die Triathlon Tritanium Basisplatte ist mit den Triathlon Kreuzband erhaltenden (CR) und den Kreuzband ersetzenden (posterior stabilisiert – PS) Designs kompatibel.

Tibiakomponenten: Die Triathlon Tritanium Basisplatte ist mit Triathlon Tibiaeinsätzen in einem Kreuzband erhaltenden (CR), posterior stabilisierenden (PS) und kondylär stabilisierenden (CS) Design kompatibel. Die Tibiaeinsätze sind in verschiedenen Stärken und mit unterschiedlichen Beweglichkeitsbegrenzungen erhältlich.

Hinweis: Der Triathlon Tritanium Basisplatte liegt ein Impaktorpad bei. Das Impaktorpad wird nur während des Einschlagens verwendet und muss nach dem Einschlagen verworfen werden. Es ist nicht zur Implantation vorgesehen.

Patellakomponenten: Patellakomponenten für den Oberflächenersatz sind in Vollkunststoff als symmetrisches und asymmetrisches Design oder metallgefüttert erhältlich. Die Verwendung einer Patellakomponente ist optional. Die Triathlon Tritanium Basisplatte ist mit allen Triathlon Patellakomponenten kompatibel.

Werkstoffe

• ASTM F-75 Kobaltchromlegierung	Femurkomponenten
• ASTM F-90 Kobaltchromlegierung	Feststelldraht für Tibiaeinsätze
• ASTM F-1537 Kobaltchromlegierung	Femurklammern
• ASTM F-136 Titanlegierung	Tibiakomponenten
• ASTM F-67 CP Titan	Tibiakomponenten
• ASTM F-1185 Calciumphosphat	Femurkomponenten, Patellakomponenten
• ASTM F-648 Polyethylen mit ultrahohem Molekulargewicht	Tibiagleitflächeneinsätze, Patellakomponenten

Indikationen

Allgemeine Totalkniearthroplastik (TKR) Indikationen:

- Schmerzhafte und behindernde Kniegelenkserkrankungen als Folge von: nichtentzündlicher, degenerativer Gelenkerkrankung (einschließlich Osteoarthrose, traumatische Arthritis und avaskulärer Nekrose), rheumatoider oder posttraumatischer Arthritis.
- Posttraumatischer Verlust von Struktur und Funktionsfähigkeit des Kniegelenks.
- Mäßige Varus-, Valgus- oder Flexionsdeformation, bei der die Ligamentstruktur wieder funktionsfähig und stabil gemacht werden kann.
- Revision eines früheren, nicht erfolgreichen Knieersatzes oder eines anderen Eingriffs.
- Fraktur des distalen Femurs und/oder der proximalen Tibia, die nicht mit Standardtechniken der Frakturversorgung stabilisiert werden kann.

Die Triathlon Tritanium Basisplatte ist sowohl für den zementfreien als auch für den zementierten Einsatz indiziert.

Zusätzliche Indikationen für posterior stabilisierte (PS) Komponenten:

- Instabile Bänderstruktur, die den Einsatz von Gleitflächen mit Oberflächengeometrien mit stärkerer Beweglichkeitseinschränkung erfordert.
- Fehlendes oder funktionsuntüchtiges hinteres Kreuzband.
- Schwere anterioposteriore Instabilität des Kniegelenks.

Kontraindikationen

- Akute oder vermutete latente Infektion des Kniegelenks oder seiner Umgebung.
- Entfernte Infektionsherde, welche die hämatogene Ausbreitung auf das Implantationsgebiet verursachen können.
- Psychische oder neuromuskuläre Störungen, welche ein inakzeptables Risiko für Stabilität oder Fixierung der Prothese oder für Komplikationen bei der postoperativen Nachsorge darstellen.
- Durch Krankheiten, Infektionen oder frühere Implantationsversuche beeinträchtigte Knochensubstanz, die für die Prothese keinen ausreichenden Halt bzw. keine ausreichende Fixierungsmöglichkeit bietet.
- Unterentwickeltes Skelett.
- Starke Labilität des Kniegelenks infolge fehlender seitlicher Kreuzbandintegrität und -funktionstüchtigkeit.
- Übergewicht. Bei übergewichtigen bzw. adipösen Patienten können Belastungen der Prothese auftreten, in deren Folge die Fixierung nachgibt oder auch die ganze Prothese versagt.

Vorsichtsmaßnahmen

- Chirurgen müssen die Patienten über die Kurz- und Langzeiteinschränkungen dieses Eingriffs aufklären, sowie der Notwendigkeit, das Implantat bis zur ausreichenden Fixierung und Heilung vor voller Belastung zu schützen. Übermäßige Aktivitäten und Trauma, welche den Hüftersatz beeinträchtigen, können durch Lockerung, Fraktur und/oder Abnutzung der Implantate zu einem Versagen der Rekonstruktion führen. Lockerung der Komponenten kann zu erhöhter Produktion von Abnutzungspartikeln sowie einer Knochenschädigung führen und eine erfolgreiche Revision erschweren.
- Chirurgen müssen die Patienten darauf hinweisen, ihre Aktivitäten einzuschränken, den Hüftersatz vor unzumutbarer Belastung zu schützen und den Anweisungen des Arztes hinsichtlich Nachsorge und Nachbehandlung zu folgen.
- Patienten sind vom Chirurgen über mögliche unerwünschte Ereignisse einschließlich der begrenzten Lebensdauer der Prothese und der Notwendigkeit der postoperativen Schonung des Implantats zu informieren. Patienten sollten vom Operateur darauf hingewiesen werden, dass das Implantat nicht die Flexibilität, Beanspruchbarkeit, Zuverlässigkeit und Widerstandsfähigkeit eines gesunden Knochens repliziert und dass es brechen oder beschädigt werden kann, besonders nach Anstrengung oder Trauma.
- Die Wahl der richtigen Komponenten für eine Knietotalprothese sowie ihre richtige Platzierung und Fixierung sind entscheidende Faktoren für die Lebensdauer der Prothese. Eine Vielzahl biologischer, biomechanischer und anderer äußerer Faktoren kann die Haltbarkeit dieser - wie aller anderen - Prothesen negativ beeinflussen. Die konsequente Beachtung aller Indikationen, Kontraindikationen, Vorsichtsmaßnahmen und Warnhinweise zu diesem Produkt ist daher für einen optimalen, anhaltenden Erfolg von größter Bedeutung.

Anwendung und Implantation

- Zur Größenbestimmung, Probeeinrichtung und Festlegung des Bewegungsbereichs sind die empfohlenen Probekomponenten zu verwenden, damit die eigentlichen Implantate in ihren sterilen Verpackungen unversehrt bleiben.
- Zur präoperativen Bestimmung von Komponentengröße und -ausführung sind Röntgenschablonen erhältlich.
- Es muss darauf geachtet werden, alle Knochensplitter, Knochenzementfragmente und Metallpartikel aus dem Implantationsbereich zu entfernen, um das Risiko einer durch Trümmerpartikel induzierten erhöhten Abnutzung der Gelenkoberflächen zu reduzieren.

- Weitere Informationen zur Operationstechnik finden sich in den chirurgischen Protokollen von Howmedica Osteonics Corp.
- Spezifische Hinweise zur Produktkompatibilität finden sich auf dem Verpackungsetikett. Im Allgemeinen gilt Folgendes:
  - PS Femurkomponenten nur mit PS Tibiagleitflächen verwenden.
  - CR Femurkomponenten nur mit CR Tibiagleitflächen verwenden.
  - Bei CS Tibiagleitflächen entweder PS oder CR Femurkomponenten verwenden.

Informationen für Patienten

- Der Chirurg muss den Patienten über die Kurz- und Langzeiteinschränkungen dieses Eingriffs aufklären, sowie der Notwendigkeit, bis zur ausreichenden Fixierung und Heilung das Implantat vor voller Belastung zu schützen. Übermäßige Aktivitäten und Trauma, welche den Hüftersatz beeinträchtigen, können durch Lockerung, Fraktur und/oder Abnutzung der Implantate zu einem Versagen der Rekonstruktion führen. Lockerung der Komponenten kann zu erhöhter Produktion von Abnutzungspartikeln sowie einer Knochenschädigung führen und eine erfolgreiche Revision erschweren.
- Der Chirurg muss Patienten darauf hinweisen, ihre Aktivitäten einzuschränken, den Hüftersatz vor unzumutbarer Belastung zu schützen und den Anweisungen des Arztes hinsichtlich Nachsorge und Nachbehandlung zu folgen.
- Der Chirurg muss den Patienten über operative Risiken und Nebenwirkungen aufklären. Der Chirurg muss dem Patienten deutlich machen, dass die Prothese nicht die Leistung eines normalen, gesunden Knochens erbringen kann, dass das Implantat infolge belastender Aktivität oder Trauma brechen oder beschädigt werden kann und dass die Prothese über eine begrenzte Lebensdauer verfügt und unter Umständen nach einer gewissen Zeit ersetzt werden muss.
- Es kann zu einer vorübergehenden Bakteriämie kommen. Zahnbehandlungen, endoskopische Untersuchungen oder kleinere chirurgische Eingriffe wurden ebenfalls mit transienter Bakteriämie in Verbindung gebracht. Um eine Infektion an der Implantationsstelle zu verhindern, kann es ratsam sein, vor und nach solchen Eingriffen eine Antibiotikaprophylaxe anzuordnen.

Warnhinweise

- Beschädigte oder fehlerhafte Komponenten verwerfen.
- Implantate niemals wieder verwenden, auch wenn sie unbeschädigt erscheinen.
- Das Impaktorpad nicht implantieren. Das Impaktorpad nur während des Einschlagens der Tibiakomponente verwenden. Sofort nach dem Impaktieren entfernen und verwerfen.
- Polierte Gleitflächen dürfen nicht mit harten oder scheuernden Oberflächen in Kontakt kommen.
- Die Gleitflächen müssen vor dem Zusammenbau sauber und frei von Geweberesten sein.
- Verformen oder Verbiegen der Komponenten kann zu Materialermüdung und zum Versagen bei Belastung führen.
- Der metallene Sicherungsdraht am Gleitflächeneinsatz dient der Sicherung der zusammengesetzten Prothese und darf nicht bewegt oder entfernt werden. Tibiagleitflächeneinsätze, bei denen der metallene Sicherungsdraht beschädigt oder verbogen erscheint, sind zu verwerfen. Jegliche Veränderung des Sicherungsrings kann zu einer Fehlfunktion des Sicherungsmechanismus führen.
- Beim Umgang mit scharfkantigen orthopädischen Prothesen ist darauf zu achten, dass die Operationshandschuhe nicht beschädigt werden.
- Sofern nicht anders angegeben, rät Howmedica Osteonics Corp. dringend davon ab, Totalkniekomponenten anderer Hersteller zusammen mit Totalkniekomponenten von Howmedica Osteonics einzusetzen. Howmedica Osteonics Corp. lehnt jede Verantwortung für die Funktionsfähigkeit einer sich daraus ergebenden Mischkomponentenprothese ab.
- Howmedica Osteonics Corp. rät dringend davon ab, Knochenschrauben anderer Hersteller zusammen mit Totalkniekomponenten von Howmedica Osteonics einzusetzen, da es unterschiedliche Auslegungen von Schraubenköpfen und -versenkungen gibt.

- Totalkniekomponenten können durch vorsichtige Anwendung von Knochenfräsen, dünnen, schmalen Osteotomen und Zugkraft explantiert werden.
- Absichtliche Entfernung des Kunststoff-Tibiaeinsatzes nach seiner Befestigung in der Basisplatte aus Metall führt zu dessen Zerstörung. Bei einer Entfernung des Einsatzes ist darauf zu achten, dass die Oberfläche der Tibiabasisplatte nicht zerkratzt oder beschädigt wird.
- Verpackungen, deren Sterilverschlüsse defekt erscheinen, an den Händler zurückgeben. **Nicht resterilisieren.**

Mögliche Folgeerscheinungen

- Die Lebensdauer der Komponenten von Knietotalprothesen ist schwer zu bestimmen, jedoch immer begrenzt. Diese Komponenten sind aus Fremdstoffen hergestellt, die in den Körper implantiert werden, um die Bewegungsfähigkeit möglichst wiederherzustellen bzw. um Schmerzen zu lindern. Diese Einheiten unterliegen zahlreichen biologischen, mechanischen und physikochemischen Faktoren, deren Untersuchung *in vivo* sich verbietet. Man kann daher nicht davon ausgehen, dass diese Komponenten auf unbegrenzte Zeit die Aktivitäten und Belastungen normaler gesunder Knochen aushalten. Chirurgen müssen Patienten dahingehend beraten, keine unrealistischen Erwartungen bezüglich der Lebensdauer des Implantats zu haben.
- Unangebrachte Aktivitäten des Patienten, Trauma und andere biomechanische Faktoren können eine Luxation der Femur-, Tibia- bzw. Patellaprothese verursachen.
- Es kann vorkommen, dass sich die Komponenten einer Knietotalprothese lockern. Mögliche Ursachen für eine frühe mechanische Lockerung sind nicht ausreichende Fixierung bei der Implantation, latente Infektionen, verfrühte Belastung der Prothese, fehlerhafte Ausrichtung der Komponenten oder Trauma. Mögliche Ursachen für eine später auftretende Lockerung sind Trauma, Infektionen, biologische Komplikationen einschließlich Osteolyse oder mechanische Probleme, was zu Knochenschwund und/oder Schmerzen führen kann.
- In einem geringen Prozentsatz aller Fälle ist ein Bruch der Kniekomponenten, einschließlich der Tibia-, Femur- und Patellakomponenten, als Folge von Materialermüdung eingetreten. Der Bruch einer Kniekomponente kann das Resultat einer unzureichenden Stützung der Komponente durch den darunter liegenden Knochen oder einer schlechten Fixierung der Komponente sein.
- Periphere Neuropathien, Nervenschäden, Kreislaufstörungen und heterotope Ossifikation können gelegentlich auftreten.
- Jeder Eingriff dieses Umfangs birgt das Risiko ernster Komplikationen. Zu diesen Komplikationen gehören vor allem Störungen des Urogenitalsystems, des Magen-Darm-Trakts, der Blutgefäße (einschl. Thrombosen), des Bronchopulmonalsystems (einschl. Embolien), Myokardinfarkt und Tod.
- Gelegentlich kommt es zur Abnutzung der Polyethylenkomponenten, die in der Literatur mit dem Auftreten von Knochenresorption, Lockerung und Infektion in Verbindung gebracht wurde.
- Es sind nach Gelenkersatz gelegentlich Empfindlichkeitsreaktionen auf Metall gemeldet worden.
- Negative Folgeerscheinungen machen u. U. eine erneute Operation, Revision, die Arthrodese des betroffenen Gelenks und/oder eine Gliedmaßenamputation erforderlich.
- Weichteilunausgewogenheit und/oder -schlaffheit wurde mit einer fehlerhaften Ausrichtung der Komponenten in Verbindung gebracht, was zu einer frühen Abnutzung und/oder einem Versagen des Implantats führen kann.
- Wie bei allen Endoprothesen kann es aufgrund von Fremdkörperreaktionen gegen Zement-, Metall-, UHMWPE- und/oder Keramikpartikel in der Umgebung der Prothesenkomponenten zu asymptomatischer, lokalisierter progressiver Knochenresorption (Osteolyse) kommen. Partikel können sich durch Interaktion der Komponenten mit dem Knochen und mit anderen Komponenten bilden, insbesondere durch Abnutzungsvorgänge wie Adhäsion, Abrieb und Materialermüdung. Außerdem können sich Partikel durch wiederholten Kontakt mit Drittmaterialien lösen. Osteolyse kann im Laufe der Zeit zu Komplikationen wie etwa Lockerung der Prothese führen, was eine Explantation und das Ersetzen von Prothesenkomponenten erforderlich macht.

- Es ist bekannt, dass die Metall- und Polyethlyenkomponenten während des normalen Gebrauchs im Laufe der Zeit sehr kleine Partikel abstoßen können. Der größte Teil dieser Materialtrümmer bleibt im jeweiligen Gelenk (z. B. von der Synovialis eingeschlossen) oder wird vom umgebenden Narbengewebe festgehalten, doch ist es möglich, dass mikroskopische Teilchen aus dem Gelenk in andere Teile des Körpers gelangen. Es gibt derzeit noch unbeantwortete Fragen hinsichtlich der Materialtrümmer und mikroskopischen Teilchen, die von diesen Komponenten erzeugt werden können. Es wurde gezeigt, dass mikroskopische Trümmerteilchen durch den ganzen Körper wandern können, und gelegentlich wurde von Ansammlungen in den Lymphknoten und anderen Körperteilen berichtet. Bisher liegen keine Berichte über signifikante medizinische Komplikationen infolge dieser Partikel vor, doch ihre Migration und/oder Ansammlung im Körper wurde in der Literatur beschrieben. Angesichts der kurzen Zeiträume, über die Patienten mit diesen Implantaten beobachtet wurden, sowie der Tatsache, dass diese Implantate gegenwärtig bei jüngeren Patienten eingesetzt werden und zunehmend länger im Körper verbleiben, ist festzustellen, dass die etwaigen Langzeitwirkungen dieser Partikel nicht bekannt sind. Zu den theoretischen Langzeitwirkungen gehören u. a.:
  - **Krebs:** Derzeit liegen keine wissenschaftlichen Beweise für eine Verbindung zwischen Metall- oder Polyethylentrümmern und Krebs vor. Die Möglichkeit kann jedoch nicht ausgeschlossen werden.
  - **Lymphknotenerkrankung und Ansammlung in anderem Gewebe bzw. anderen Organen:** Es liegen einige wenige Berichte über die Ansammlung von verschleißbedingten Trümmern in Lymphknoten (proximal und distal) vor. Obwohl keine medizinischen Komplikationen oder Krankheitsverläufe auf diese Ansammlungen zurückgeführt wurden, muss ihre Anwesenheit erkannt werden, um die Diagnose zu erleichtern und eine Verwechslung mit verdächtigen Läsionen, karzinomatös oder nicht, zu vermeiden.
  - **Systemerkrankung:** Es gibt einige Spekulationen über einen möglichen Zusammenhang zwischen der Migration von Materialtrümmern und noch nicht spezifizierten systemischen Auswirkungen. Es ist möglich, dass irgendwann in der Zukunft bestimmte Langzeitauswirkungen nachgewiesen werden, doch angesichts des Mangels an wissenschaftlichen Daten, die auf eine Verbindung zwischen der Migration von Materialtrümmern und Systemerkrankung hinweisen, wird angenommen, dass die Vorteile dieser Implantate die möglichen Risiken solcher theoretischen Langzeitwirkungen klar überwiegen.

Wechselwirkung mit der Kernspintomografie

Das Triathlon Kniesystem wurde nicht auf Sicherheit und Kompatibilität im MRT-Umfeld evaluiert. Das Triathlon Kniesystem wurde nicht auf Erwärmung oder Migration im MRT-Umfeld getestet.

Sterilisierung

- Diese Totalkniekomponente wurde mit Gamma-Strahlung oder Hydrogenperoxid-Plasma sterilisiert. Das Sterilisierverfahren ist auf dem Verpackungsetikett angegeben.
- Vor dem Öffnen einer Sterilpackung ist die Verpackung grundsätzlich auf eventuelle Beschädigungen des Sterilschutzes zu prüfen. Bei Vorliegen einer Beschädigung ist das Produkt als unsteril zu betrachten. Zur Vermeidung einer auch teilweisen vorzeitigen Öffnung der Sterilverpackung vor der Verwendung der betreffenden Komponente sind spezielle Probeprothesen verfügbar.
- Jede Kontaminierung der Komponenten ist zu vermeiden. Kontaminierte Komponenten sind zu verwerfen.
- Unbenutzte Produkte in geöffneten Packungen auf keinen Fall erneut sterilisieren, sondern wegwerfen oder an den Händler zurückgeben.
- Das Implantat nicht nach dem auf dem Etikett angegebenen Verfallsdatum verwenden, da die Verpackung nicht über dieses Datum hinaus validiert wurde.
- Einmalprodukte können nicht explantiert und anschließend reimplantiert werden, da die durch diese Verfahren ausgeübten physikalischen Kräfte die physikalische Integrität, Abmessungen und/oder Oberflächenausführungen der Implantate beeinträchtigen können. Darüber hinaus kann für wieder verwendete Implantate keine Sterilität gewährleistet werden, da Reinigungs- und Resterilisationsverfahren nicht verifiziert wurden.

ACHTUNG: **NACH US-BUNDESGESETZ DARF DIESE VORRICHTUNG NUR VON EINEM ARZT ODER AUF VERORDNUNG EINES ARZTES VERKAUFT WERDEN.**

WARNUNG: Komponenten, die mit "Nur mit Zementierung verwenden" gekennzeichnet sind, dürfen nur mit Knochenzement implantiert werden.

Den Status der CE-Kennzeichnung sowie den Hersteller finden Sie auf dem Produktetikett. Die CE-Kennzeichnung ist nur dann gültig, wenn sie ebenfalls auf dem Produktetikett erscheint.

Die folgende Tabelle enthält eine Liste mit Abkürzungen, die von Howmedica Osteonics Corp. für die Produktetikettierung verwendet wird:

Abkürzung	Bezeichnung	Abkürzung	Bezeichnung
Alpha-Code	ALPH CDE	Hals	NK
Winkel	ANG	Versetzt	OFFST
Grad	DEG or °	Außendurchmesser	OD
Durchmesser	DIA	Rechts	RT ▶
Extratief	XDP	Bohrungen	SCR HLS
Extragroß	XLGE	Seite	SDE
Extraklein	XSM	Größe	SZE
Kopf	HD	Klein	SM
Höhe	HT	Standard	STD
Innendurchmesser	ID	Konus	TPR
Einsatz	INSR	Dicke	THKNS
Groß	LGE	Typ	TYP
Links	◀ LFT	Mit	W/
Länge	LNTH	Ohne	W/O
Mittel	MED		

Italiano

ARTROPLASTICA TOTALE DEL GINOCCHIO TRIATHLON TRITANIUM DI HOWMEDICA OSTEONICS - ISTRUZIONI PER L'USO

Descrizione

I sistemi di artroplastica totale del ginocchio Howmedica Osteonics Corp. comprendono la base Triathlon Tritanium, progettata per essere utilizzata con i componenti femorali, gli inserti tibiali e i componenti patellari del sistema di artroplastica primaria del ginocchio Triathlon per la sostituzione ricostruttiva totale dell'articolazione del ginocchio. Le caratteristiche specifiche di ogni dispositivo sono descritte in maniera particolareggiata sull'etichetta del prodotto. La base Triathlon Tritanium è indicata sia per le applicazioni senza cemento, sia per quelle con cemento.

Componenti femorali: La base Triathlon Tritanium è compatibile con i modelli Triathlon per la ritenzione del legamento crociato (CR) e per il sacrificio del legamento crociato (stabilizzato posteriormente - PS).

Componenti tibiali: La base Triathlon Tritanium è compatibile con gli inserti tibiali Triathlon nei modelli per la ritenzione del legamento crociato (CR), stabilizzato posteriormente (PS) e con stabilizzazione condilare (CS). Gli inserti tibiali sono disponibili in vari spessori e con diversi gradi di costrizione.

Nota: la confezione della base Triathlon Tritanium contiene un cuscinetto impattatore, che deve essere utilizzato esclusivamente nella fase di collimazione della base tibiale e deve essere smaltito una volta completata tale operazione. Il cuscinetto impattatore non è destinato all'impianto.

Componenti patellari: I componenti patellari di rivestimento sono disponibili nei modelli completamente in plastica simmetrici e asimmetrici e con rinforzo metallico. L'uso di un componente patellare è opzionale. La base Triathlon Tritanium è compatibile con tutti i componenti patellari Triathlon.

Materiali

• Lega di cromo-cobalto ASTM F-75	Componenti femorali
• Lega di cromo-cobalto ASTM F-90	Filo di bloccaggio per inserti tibiali
• Lega di cromo-cobalto ASTM F-1537	Perni femorali
• Lega di titanio ASTM F-136	Componenti tibiali
• Titanio CP ASTM F-67	Componenti tibiali
• Fosfato di calcio ASTM F-1185	Componenti femorali, componenti patellari
• Polietilene ad altissimo peso molecolare (UHMWPE) ASTM F-648	Inserti di supporto tibiale, componenti patellari

Indicazioni

Indicazioni per l'artroplastica totale generale del ginocchio (TKR):

- Patologia dolorosa e invalidante dell'articolazione del ginocchio dovuta a: artropatia degenerativa dell'articolazione non infiammatoria (comprese osteoartrite, artrite traumatica o necrosi avascolare), artrite reumatoide o artrite post-traumatica.
- Perdita post-traumatica della configurazione e della funzione dell'articolazione del ginocchio.
- Varo, valgo o deformità di flessione moderati, tali da consentire di restituire funzione e stabilità adeguate alle strutture legamentose.
- Revisione di un precedente insuccesso di artroplastica totale del ginocchio o di altre procedure.
- Frattura del femore distale e/o della tibia prossimale che non può essere stabilizzata dalle tecniche standard di gestione delle fratture.

La base Triathlon Tritanium è indicata per l'uso sia senza cemento, sia con cemento.

Ulteriori indicazioni per i componenti stabilizzati posteriormente (PS):

- Instabilità legamentosa che richieda geometrie di superficie di supporto dell'impianto con maggiore grado di costrizione.
- Legamento crociato posteriore assente o non funzionante.
- Grave instabilità anteroposteriore dell'articolazione del ginocchio.

Controindicazioni

- Qualsiasi infezione latente, attiva o sospetta, nell'articolazione del ginocchio o nella zona circostante.
- Focolai di infezioni distanti (che possono provocare diffusione ematogena al sito dell'impianto).
- Qualsiasi problema psichico o neuromuscolare che possa comportare un rischio inaccettabile di instabilità della protesi, mancato fissaggio della protesi o complicanze postoperatorie.
- Struttura ossea compromessa da patologia, infezione o impianto precedente e pertanto incapace di fornire adeguato sostegno e/o fissaggio alla protesi.
- Immaturità scheletrica.
- Grave instabilità dell'articolazione del ginocchio dovuta a mancata integrità e funzione del legamento collaterale.
- Obesità. Un paziente che sia sovrappeso o obeso può gravare la protesi di un carico capace di provocare il mancato fissaggio dell'impianto o il fallimento dell'impianto stesso.

Precauzioni

- I chirurghi devono avvisare i pazienti delle limitazioni della ricostruzione e della necessità di proteggere l'impianto da eccessivi carichi fino a quando non sia avvenuto un adeguato fissaggio e guarigione. È stato dimostrato che un'eccessiva attività o traumi subiti dall'impianto sono fattori responsabili del fallimento di un intervento ricostruttivo per allentamento, frattura e/o usura dell'impianto protesico. L'allentamento dei componenti protesici può portare ad una maggiore produzione di particelle dovute all'usura, oltre a danni all'osso stesso, che renderebbero più difficile la riuscita dell'operazione chirurgica di revisione.
- I chirurghi devono consigliare ai pazienti di limitare l'attività fisica e di proteggere l'articolazione sostituita da eccessivi e irragionevoli sforzi e di seguire le istruzioni del medico per quanto concerne le cure di follow-up.
- I chirurghi dovranno segnalare ai pazienti i potenziali effetti avversi, incluso il fatto che il dispositivo ha una durata non infinita e che sarà necessaria una protezione postoperatoria dell'impianto. Il chirurgo deve avvertire i pazienti del fatto che il dispositivo non può riprodurre la flessibilità, la robustezza, l'affidabilità o la durata di un'articolazione sana e normale, che l'impianto potrebbe anche rompersi o essere danneggiato come conseguenza di un'eccessiva attività o di traumi.
- Scelta, sistemazione e fissaggio opportuni dei componenti dell'artroplastica totale del ginocchio sono fattori critici che incidono sulla durata dell'impianto. Come per tutti gli impianti protesici, la durevolezza di tali componenti può essere compromessa da numerosi fattori biologici, biomeccanici e di carattere estrinseco, che ne limitano il rendimento. Di conseguenza, è importante attenersi rigorosamente alle indicazioni, controindicazioni, precauzioni e avvertenze di questo prodotto, onde prolungare al massimo la durata dell'impianto.

Utilizzo e impianto

- I componenti di prova raccomandati devono essere usati per determinare la misura, per effettuare una riduzione di prova e per valutare il raggio di movimento, conservando in tale modo l'integrità degli impianti definitivi, nonché la sterilità della confezione.
- I modelli radiografici sono disponibili come ausilio nella pianificazione preoperatoria relativa alle dimensioni e al tipo dei componenti.
- Fare particolare attenzione nella rimozione di frammenti d'osso, frammenti di cemento e detriti metallici dal sito dell'impianto onde ridurre il rischio di presenza di detriti che accelerino l'usura delle superfici articolari dell'impianto.

- I protocolli chirurgici di Howmedica Osteonics Corp. forniscono ulteriori informazioni sulle procedure.
- Consultare l'etichetta del prodotto per la compatibilità specifica del prodotto. In linea generale valgono i seguenti criteri:
  - Utilizzare componenti femorali PS esclusivamente con supporti tibiali PS
  - Utilizzare componenti femorali CR esclusivamente con supporti tibiali CR
  - Utilizzare componenti femorali PS o CR con supporti tibiali CS

Informazioni per i pazienti

- Il chirurgo deve avvisare il paziente delle limitazioni della ricostruzione e della necessità di proteggere l'impianto da eccessivi carichi fino a quando non siano avvenuti un fissaggio e una guarigione adeguati. È stato dimostrato che un'eccessiva attività o traumi subiti dall'impianto sono fattori responsabili del fallimento di un intervento ricostruttivo per allentamento, frattura e/o usura dell'impianto protesico. L'allentamento dei componenti protesici può portare ad una maggiore produzione di particelle dovute all'usura, oltre a danni all'osso stesso, che renderebbero più difficile la riuscita dell'operazione chirurgica di revisione.
- Il chirurgo deve consigliare al paziente di limitare l'attività fisica e di proteggere l'articolazione sostituita da eccessivi e irragionevoli sforzi e di seguire le istruzioni del medico per quanto concerne le cure di follow-up.
- Il chirurgo deve avvertire il paziente dei rischi chirurgici e dei possibili effetti avversi. Il chirurgo deve avvertire il paziente del fatto che la protesi impiantata non è l'equivalente di un'articolazione sana e normale, che l'impianto potrebbe anche rompersi o essere danneggiato come conseguenza di un'eccessiva attività o di traumi e che l'impianto ha una durata limitata nel tempo e potrebbe aver bisogno di essere sostituito in futuro.
- Una batteriemia transitoria può verificarsi nel corso della vita di tutti i giorni. Interventi odontoiatrici, esami endoscopici e altre procedure chirurgiche d'importanza minore sono state associate alle batteriemie transitorie. Per prevenire infezioni al sito d'impianto, deve essere seguita una profilassi con l'uso di antibiotici prima e dopo gli interventi che possono dare luogo a batteriemia.

Avvertenze

- Eliminare tutti gli impianti danneggiati o maneggiati in modo sbagliato.
- Non riutilizzare mai un impianto, anche se può sembrare non danneggiato.
- Non impiantare il cuscinetto impattatore, che deve essere utilizzato esclusivamente nella fase di collimazione tibiale e deve essere rimosso e smaltito non appena completata tale operazione.
- Le zone di supporto lucidate non devono mai entrare in contatto con superfici dure o abrasive.
- Le zone di supporto devono essere sempre pulite e libere da detriti prima di iniziare l'assemblaggio.
- Il piegamento o l'incurvatura di un impianto possono ridurne la resistenza alla fatica e provocarne il fallimento sotto carico.
- Il filo metallico di ritenzione sull'inserto non deve essere maneggiato o rimosso, essendo un elemento di importanza vitale per la sicurezza della protesi. Se il filo metallico di ritenzione appare danneggiato o maneggiato in modo sbagliato, l'inserto non deve essere utilizzato. La manomissione di tale sistema può causare il malfunzionamento del meccanismo di ritenzione.
- Fare attenzione onde evitare di tagliare i guanti chirurgici durante la manipolazione di apparecchi ortopedici con bordi affilati.
- Eccetto quando indicato diversamente, Howmedica Osteonics Corp. sconsiglia vivamente l'utilizzo, assieme ad un componente Howmedica Osteonics, di un componente per artroplastica totale del ginocchio di un altro produttore. Tale sostituzione invaliderebbe ogni responsabilità da parte di Howmedica Osteonics Corp. circa il rendimento dell'impianto formato da componenti misti.
- Howmedica Osteonics Corp. raccomanda vivamente di non usare viti per ossa di altri produttori con alcun componente Howmedica Osteonics per l'artroplastica totale del ginocchio, a causa delle variazioni esistenti tra la configurazione della testa e quella della sede delle viti.

- La rimozione intenzionale di un componente per l'artroplastica totale del ginocchio può essere effettuata utilizzando, con la debita attenzione, lime o osteotomi stretti e sottili e applicando forze di estrazione molto delicate.
- La rimozione intenzionale di un inserto tibiale in polietilene, dopo che sia stato montato sulla base metallica, provoca la distruzione dell'inserto stesso. Occorre prestare attenzione onde evitare di ammaccare o scheggiare la superficie della base tibiale durante la rimozione dell'inserto.
- Rinviare al fornitore ogni confezione difettosa nel proprio involucro sterile. **Non risterilizzare.**

Effetti avversi

- È difficile prevedere la durata dei componenti per l'artroplastica totale del ginocchio, ma sappiamo che non è indefinita. Questi componenti sono prodotti con materiali estranei che vengono inseriti all'interno dell'organismo per il ripristino potenziale della mobilità o la riduzione di condizioni dolorose. A causa però dei tanti fattori biologici, meccanici e fisicochimici che hanno effetto su questi dispositivi ma che non possono essere valutati *in vivo*, i componenti non possono durare a tempo indefinito con un livello di attività e di carico simile a quelli di una struttura ossea sana e normale. I chirurghi devono avvisare il paziente affinché non nutra aspettative poco realistiche sulla durata del dispositivo.
- Può verificarsi una lussazione della protesi femorale, tibiale o patellare dovuta ad attività inopportuna del paziente, trauma o altri fattori di origine biomeccanica.
- Può verificarsi l'allentamento dei componenti dell'artroplastica totale del ginocchio. L'allentamento meccanico prematuro può essere dovuto ad un fissaggio iniziale inadeguato, infezione latente, caricamento prematuro della protesi, cattivo allineamento dei componenti o trauma. Un allentamento tardivo può essere conseguenza di trauma, infezione, complicanze biologiche, compresa l'osteolisi, o di problemi di origine meccanica, con la possibilità di causare successivamente l'erosione del tessuto osseo e/o dolore.
- In una bassa percentuale di casi si è verificata la frattura per fatica dei componenti per l'artroplastica totale del ginocchio, compresi i componenti tibiale, femorale e patellare. La frattura dei componenti del ginocchio può essere conseguenza di un supporto inadeguato del componente da parte della struttura ossea sottostante o del cattivo fissaggio del componente.
- Possono verificarsi neuropatie periferiche, danni ai nervi, problemi vascolari e formazione di tessuto osseo eterotopico.
- Gravi complicanze possono essere associate a qualsiasi intervento chirurgico di artroplastica totale. Tali complicanze includono (elenco non esaustivo): disturbi genitourinari; gastrointestinali; vascolari, inclusi trombi; disturbi broncopolmonari, inclusi emboli; infarto del miocardio o decesso.
- In passato si è verificato il logorio dei componenti di polietilene e la documentazione medica ha collegato tale fenomeno a riassorbimento del tessuto osseo, allentamento e infezione.
- Sono state riportate reazioni di sensibilità ai metalli in seguito ad interventi di artroplastica sostitutiva.
- Alcuni effetti avversi possono richiedere reintervento, revisione, artrodesi dell'articolazione interessata e/o amputazione dell'arto.
- Squilibrio e/o rilassamento dei tessuti molli sono stati collegati a cattivo allineamento dei componenti, con conseguente possibile usura precoce e/o fallimento dell'impianto.
- Con tutti gli impianti può verificarsi il riassorbimento osseo (osteolisi) asintomatico, localizzato e progressivo intorno ai componenti protesici come conseguenza della reazione dell'organismo ai corpi estranei e specificamente alla materia particellare del cemento, del metallo, del polietilene ad altissimo peso molecolare (UHMWPE) e/o della ceramica. La materia particellare è generata dall'interazione tra i componenti, come pure tra i componenti e l'osso, principalmente attraverso il meccanismo di usura per adesione, abrasione e sforzo. Secondariamente, la materia particellare può essere generata anche da usura per contatto con corpi estranei. L'osteolisi può portare a complicanze future, compreso l'allentamento, rendendo quindi necessaria la rimozione e la sostituzione di componenti protesici.
- È noto che minuscole particelle di metallo e polietilene possono staccarsi dai componenti durante un normale utilizzo e nel corso del tempo. Anche se la maggior parte dei detriti rimane nella relativa articolazione (ad esempio nella sinoviale) o rimane inglobata nel tessuto cicatriziale circostante, particelle

microscopiche possono spostarsi o migrare all'esterno dell'articolazione in varie parti dell'organismo. Attualmente esistono domande irrisolte sui detriti e le particelle microscopiche che possono essere generate da questi componenti. È stato dimostrato che particelle microscopiche di detriti possono disseminarsi (migrare) nell'organismo e in alcuni casi è stato descritto il loro accumulo in nodi linfatici e altre parti dell'organismo. Anche se, a oggi, non sono state riferite complicanze mediche significative quale risultato di queste particelle, la loro migrazione e/o accumulo nell'organismo sono stati descritti in letteratura. Dato il periodo di tempo insufficiente di follow-up di pazienti con questi dispositivi e poiché questi dispositivi vengono correntemente usati anche in pazienti più giovani rimanendo nel corpo per periodi di tempo sempre più lunghi, si può affermare che gli eventuali effetti a lungo termine di queste particelle sono sconosciuti. Gli effetti a lungo termine concepiti a livello teorico comprendono:

- **Cancro:** al momento non vi è evidenza scientifica che consenta una correlazione fra detriti metallici o di polietilene e cancro. Tuttavia, la possibilità non può essere esclusa.
- **Linfoadenopatia e accumulo in altri tessuti/organi:** vi sono state alcune segnalazioni di accumulo di detriti da usura in linfonodi (prossimali e distali). Anche se non sono state riferite complicanze mediche o processi patologici derivanti da tali accumuli, la loro esistenza deve essere individuata in modo da facilitare la diagnosi ed evitare confusione con lesioni sospette, cancerose o quant'altro.
- **Malattia sistemica:** è stata ipotizzata la possibilità di un collegamento fra la migrazione dei detriti ed effetti sistemici ancora non specificati. È possibile che alcuni effetti a lungo termine possano essere dimostrati ad un certo punto in futuro, ma poiché esistono pochissimi dati scientifici che suggeriscano un collegamento fra la migrazione dei detriti e la malattia sistemica, si ritiene che i benefici di questi dispositivi siano nettamente superiori ai potenziali rischi relativi ad ognuno degli eventuali effetti teorici a lungo termine.

Interazione con l'imaging a risonanza magnetica

Il sistema di artroplastica totale del ginocchio Triathlon non è stato valutato per quanto riguarda la sicurezza e la compatibilità nell'ambiente RM. Il sistema di artroplastica totale del ginocchio Triathlon non è stato collaudato per quanto riguarda il riscaldamento o la migrazione nell'ambiente RM.

Sterilizzazione

- Il presente componente per l'artroplastica totale del ginocchio è stato sterilizzato con raggi gamma o con plasma gassoso a base di perossido di idrogeno. Consultare l'etichetta della confezione per il metodo di sterilizzazione.
- La confezione di tutti i prodotti sterili deve essere ispezionata prima dell'apertura per assicurarsi che la barriera sterile sia intatta e senza difetti. Se l'involucro si presenta difettoso, il prodotto è da ritenersi non sterile. Sono disponibili speciali protesi di prova in modo da poter evitare di aprire l'involucro sterile prima di utilizzare il componente.
- Fare particolare attenzione onde evitare di contaminare il componente. Nell'eventualità di contaminazione, sarà necessario eliminare il prodotto.
- Se la confezione viene aperta ma il prodotto non viene utilizzato, il componente non deve essere risterilizzato ma eliminato o rinviato al fornitore.
- Il dispositivo non deve essere utilizzato dopo la data di scadenza visualizzata sull'etichetta, in quanto la confezione non è stata omologata oltre tale data.
- I dispositivi monouso non possono essere espiantati e successivamente reimpiantati, in quanto le forze fisiche esercitate da tali azioni potrebbero compromettere l'integrità fisica, le dimensioni e/o le rifiniture superficiali dei dispositivi. Inoltre, non è possibile garantire la sterilità per i dispositivi riutilizzati, in quanto le procedure di pulizia e di risterilizzazione non sono state verificate.

ATTENZIONE: **A NORMA DELLA LEGGE FEDERALE STATUNITENSE, QUESTO DISPOSITIVO PUÒ ESSERE VENDUTO ESCLUSIVAMENTE DA UN MEDICO O SU ORDINE DI TALE MEDICO.**

AVVERTENZA: I componenti etichettati "Esclusivamente per uso con cemento" devono essere impiantati esclusivamente con cemento osseo.

Stryker Corporation (o sue divisioni o altre entità aziendali affiliate) possiede, utilizza o applica i seguenti marchi di fabbrica: Howmedica, Osteonics, Stryker, Triathlon. Tutti gli altri marchi di fabbrica o di servizio sono marchi registrati e di servizio dei rispettivi proprietari o titolari.

Fare riferimento all'etichetta del prodotto per lo stato del marchio CE e il produttore legale. Il marchio CE è valido soltanto se riprodotto anche sull'etichetta del prodotto.

La tabella seguente contiene un elenco delle abbreviazioni inglesi usate nell'etichettatura dei prodotti di Howmedica Osteonics Corp. :

Termine	Abbreviazione	Termine	Abbreviazione
Codice alfa	ALPH CDE	Collo	NK
Angolo	ANG	Offset	OFFST
Grado	DEG or °	Diametro esterno	OD
Diametro	DIA	Destro	RT ▶
Extra profondo	XDP	Fori di vite	SCR HLS
Extra grande	XLGE	Lato	SDE
Extra piccolo	XSM	Misura	SZE
Testa	HD	Small	SM
Altezza	HT	Standard	STD
Diametro interno	ID	Conico	TPR
Inserto	INSR	Spessore	THKNS
Large	LGE	Tipo	TYP
Sinistro	◀ LFT	Con	W/
Lunghezza	LNTH	Senza	W/O
Medio	MED		

Español

INFORMACIÓN PARA EL USO DE LA RÓTULA TOTAL TRIATHLON TRITANIUM DE HOWMEDICA OSTEONICS

Descripción

Los sistemas rotulianos totales de Howmedica Osteonics Corp. incluyen la placa de asiento Triathlon Tritanium, que está destinada a usarse con los componentes femorales, insertos tibiales y componentes rotulianos del sistema rotuliano primario Triathlon, para el reemplazo reconstructivo total de la articulación de la rodilla. Las características específicas para cada dispositivo se detallan en la etiqueta del producto. La placa de asiento Triathlon Tritanium está indicada para aplicaciones sin y con cemento.

Componentes femorales: La placa de asiento Triathlon Tritanium es compatible con los diseños de retención del ligamento cruciforme Triathlon (CR) y de sacrificio del ligamento (estabilizado posteriormente: PS).

Componentes tibiales: La placa de asiento Triathlon Tritanium es compatible con los insertos tibiales en un diseño de retención del ligamento cruciforme (CR), de estabilización posterior estabilizada (PS) y de estabilización condílea (CS). Los insertos tibiales están disponibles en una variedad de grosores y varios grados de restricción.

Nota: La placa de asiento Triathlon Tritanium se empaca junto con una almohadilla de impacto. La almohadilla de impacto debe usarse durante el paso de impacto de la placa de asiento tibial solamente, y debe desecharse una vez que tal impacto se haya completado. La almohadilla de impacto no está destinada para la implantación.

Componentes rotulianos: Los componentes de correcciòn superficial de rótula están disponibles en diseños simétricos y asimétricos de material plástico y con refuerzo metálico. El uso de un componente rotuliano es optativo. La placa de asiento Triathlon Tritanium es compatible con todos los componentes rotulianos Triathlon.

Materiales

• Aleación de cromo cobalto ASTM F-75	Componentes femorales
• Aleación de cromo cobalto ASTM F-90	Alambre de traba para insertos tibiales
• Aleación de cromo cobalto ASTM F-1537	Clavijas femorales
• Aleación de titanio ASTM F-136	Componentes tibiales
• Titanio CP ASTM F-67	Componentes tibiales
• Fosfato de calcio ASTM F-1185	Componentes femorales, componentes rotulianos
• Polietileno de peso molecular ultra alto ASTM F-648	Insertos de soporte tibial, componentes rotulianos

Indicaciones

Indicaciones generales para artroplastia rotuliana total (ART):

- Enfermedad dolorosa e incapacitante de la articulación de la rodilla causada por enfermedad articular degenerativa no inflamatoria (incluso artrosis, artritis traumática o necrosis avascular), artritis reumatoide o artritis postraumática.
- Pérdida postraumática de la configuración y función de la articulación de la rodilla.
- Varo, valgo o deformación de la flexión moderados, en que las estructuras ligamentosas pueden recobrar una función y estabilidad adecuadas.
- Revision de fracaso de cirugía previa de reemplazo rotuliano o de otro procedimiento.
- Fractura del fémur distal y/o la tibia proximal, que no puede estabilizarse mediante técnicas normales de tratamientos para fracturas.

La placa de asiento Triathlon Tritanium está indicada para el uso sin y con cemento.

Indicaciones adicionales para los componentes estabilizados posteriormente (PS).

- Inestabilidad ligamentosa que requiere un implante con geometrías de superficie con mayor restricción.
- Ligamento cruciforme posterior ausente o que no funciona.
- Grave inestabilidad anteroposterior de la articulación rotuliana.

Contraindicaciones

- Cualquier infección activa o sospecha de infección latente en la articulación rotuliana o tejidos adyacentes.
- Focos distantes de infección que pudieran causar una difusión hematógena al sitio del implante.
- Trastorno mental o neuromuscular que cause un riesgo inaceptable de inestabilidad de la prótesis, pérdida de la fijación de la prótesis o complicaciones durante el cuidado postoperatorio.
- Masa ósea comprometida por enfermedad, infección o implantación previa, que no puede proporcionar un apoyo o fijación adecuados de la prótesis.
- Esqueleto inmaduro.
- Inestabilidad grave de la articulación rotuliana, secundaria a la ausencia de integridad y función del ligamento colateral.
- Obesidad. Un paciente con sobrepeso u obeso puede producir cargas sobre la prótesis que pueden conducir al fracaso de la fijación del dispositivo o fracaso del dispositivo en sí.

Precauciones

- Los cirujanos deben advertir a los pacientes en lo que respecta a las limitaciones de la reconstrucción, y a la necesidad de proteger al implante contra el apoyo del peso completo hasta no haberse obtenido una fijación y cicatrización adecuadas. La actividad excesiva y los traumatismos que afectan el reemplazo de la articulación han sido implicados en el fracaso de la reconstrucción debido a aflojamiento, fractura y/o desgaste de los implantes protésicos. El aflojamiento de los componentes puede dar lugar a una mayor producción de partículas de desgaste, así como causar daño al hueso, dificultando aún más el éxito de una cirugía de revisión.
- Los cirujanos deben advertir a los pacientes que limiten las actividades y protejan a la articulación reemplazada contra tensiones irrazonables, y que deben cumplir las instrucciones del médico con respecto al cuidado y tratamiento de seguimiento.
- Los cirujanos deben advertir a los pacientes acerca de los efectos adversos potenciales, incluso la vida de servicio finita, y de la necesidad de protección postoperatoria del implante. El cirujano debe advertir a los pacientes que el dispositivo no replica la flexibilidad, resistencia, fiabilidad o duración de una articulación sana normal, y de que el implante puede romperse o dañarse como resultado de una actividad vigorosa o traumatismo.
- La selección, colocación y fijación adecuadas de los componentes rotulianos totales constituyen factores críticos que afectan la duración del implante. Como es el caso de todos los implantes protésicos, la duración de estos componentes está afectada por numerosos factores biológicos, biomecánicos y otros factores extrínsecos que limitan su duración. Según esto, es esencial que se respeten todas las indicaciones, contraindicaciones, precauciones y advertencias para este producto a fin de aumentar al máximo su duración potencial.

Utilización e implantación

- Se deben usar los componentes de ensayo recomendados para determinar el tamaño, probar la reducción y hacer una evaluación de la amplitud del movimiento, ayudando así a conservar la integridad de los implantes reales y de su envase estéril.
- Se dispone de plantillas radiográficas para ayudar a pronosticar el tamaño y estilo del componente antes de la cirugía.
- Se debe tener cuidado de extraer las astillas de hueso, fragmentos de cemento óseo y desechos metálicos del sitio del implante, a fin de reducir el riesgo de un desgaste articular acelerado del implante causado por tales desechos.

- Los protocolos quirúrgicos de Howmedica Osteonics Corp. proporcionan información adicional sobre los métodos.
- Consulte la etiqueta del producto para buscar compatibilidad específica para el producto. Generalmente se aplica lo siguiente:
  - Use femorales PS solamente con cojinetes tibiales PS.
  - Use femorales CR solamente con cojinetes tibiales CR
  - Use femorales PS o CR con cojinetes tibiales CS

Información para pacientes

- El cirujano debe advertir al paciente tanto acerca de las limitaciones de la reconstrucción como de la necesidad de proteger al implante contra el apoyo del peso completo hasta no haberse obtenido una fijación y cicatrización adecuadas. Un exceso de actividad y traumatismos afectando a la articulación sustituida han sido implicados en el fracaso de la reconstrucción debido a aflojamiento, fractura y/o desgaste de la prótesis implantada. El aflojamiento de los componentes puede dar lugar a un aumento de producción de partículas por roce, así como a daño del hueso, haciendo más difícil realizar con éxito una cirugía de revisión.
- El cirujano debe advertir al paciente que limite sus actividades y que la articulación sustituida necesita ser protegida contra los esfuerzos injustificados, así como que debe acatar las instrucciones del cirujano respecto a los cuidados y el tratamiento a seguir.
- El cirujano debe advertir al paciente sobre los riesgos quirúrgicos y los posibles efectos adversos. El cirujano debe advertir al paciente de que la prótesis no es igual a una articulación sana normal, que el implante se puede romper o dañarse a causa de la actividad vigorosa o traumatismos, y que el dispositivo tiene una vida útil limitada que, en el futuro, podría necesitar su sustitución.
- En la vida diaria es posible contraer una bacteriemia pasajera. La manipulación dental, los exámenes endoscópicos y otros procedimientos quirúrgicos menores también se han asociado con bacteriemia pasajera. Para ayudar a prevenir la infección en el sitio de la implantacion puede ser aconsejable usar profilaxis antibiótica antes y después de dichos procedimientos.

Advertencias

- Deseche todos los implantes dañados o aparentemente descuidados.
- Nunca vuelva a usar un implante aunque parezca que no esté dañado.
- No implante la almohadilla de impacto. La almohadilla de impacto debe usarse solamente durante el paso de impactación tibial. Quítela y deséchela inmediatamente después del proceso de impactación.
- No permita que las áreas de soporte pulidas entren en contacto con superficies duras o abrasivas.
- Las áreas de apoyo siempre deben estar limpias y libres de desechos antes de su ensamblaje.
- El torneado o curvado de un implante puede reducir su resistencia a la fatiga y causar un fracaso estructural bajo cargas.
- El alambre metálico de retención en el inserto no debe manipularse ni extraerse, ya que es de importancia fundamental para la seguridad del montaje. Deseche cualquier inserto de apoyo tibial si el alambre metálico de retención parece estar dañado o haber sido maltratado. La manipulación de este montaje puede dar lugar a que la función del mecanismo de retención sea inapropiada.
- Se debe tener cuidado de no dañar los guantes de cirugía a consecuencia de la manipulación de dispositivos ortopédicos afilados o cortantes.
- Excepto cuando se menciona específicamente, Howmedica Osteonics Corp. aconseja firmemente no usar componente rotuliano total alguno de otro fabricante con cualquiera de los componentes rotulianos totales de Howmedica Osteonics. Cualquier uso de este tipo anulará la responsabilidad de Howmedica Osteonics Corp. acerca del rendimiento del implante mixto resultante.
- Howmedica Osteonics Corp. recomienda firmemente no usar tornillos óseos de otros fabricantes con componentes del sistema rotuliano total de Howmedica Osteonics debido a las variaciones que existen entre las configuraciones de la cabeza y el asiento de los tornillos.

- La extracción intencional de un componente rotuliano total puede lograrse mediante el uso cauteloso de buriles de corte, osteótomos delgados y estrechos, y fuerzas de extracción cautelosas.
- La extracción intencional del inserto de plástico tibial, después de habérselo montado en la placa de asiento metálica, resulta en la destrucción del inserto de plástico. Se debe tener cuidado de no ranurar ni mellar la superficie de la placa de asiento tibial durante la extracción del inserto.
- Devuelva al abastecedor todos los empaques con fallas en la barrera estéril. **No vuelva a esterilizar.**

Efectos adversos

- Aunque la vida útil de los componentes de reemplazo rotuliano total es difícil de calcular es, sin embargo, limitada. Estos componentes se fabrican con materias extrañas que se colocan dentro del cuerpo para restaurar potencialmente la movilidad o reducir el dolor. Sin embargo, debido a los numerosos factores biológicos, mecánicos y fisicoquímicos que pueden afectar a estos dispositivos, pero que no pueden evaluarse *in vivo*, no se puede esperar que los componentes soporten indefinidamente el nivel de actividad y las cargas que soporta el hueso sano normal. Los cirujanos deben aconsejar a los pacientes que no esperen resultados no realistas acerca de la vida útil del dispositivo.
- Puede ocurrir dislocación de la prótesis femoral, tibial o rotuliana debido a la actividad inapropiada del paciente, a traumatismo o a otras consideraciones biomecánicas.
- Puede ocurrir aflojamiento de los componentes rotulianos totales. Se puede producir un aflojamiento mecánico prematuro debido a una fijación inicial inadecuada, infección latente, carga prematura de la prótesis, alineación defectuosa de un componente, o traumatismo. Se puede producir un aflojamiento tardío a causa de trauma, infección, complicaciones biológicas con inclusión de osteólisis, o problemas mecánicos, con la subsiguiente posibilidad de erosión del hueso o de que se produzca dolor.
- En un pequeño porcentaje de casos ocurrió fractura de los componentes rotulianos totales, incluso componentes tibiales, femorales y rotulianos. La fractura de los componentes rotulianos puede ocurrir debido a soporte inadecuado del componente por el hueso subyacente o por fijación deficiente del componente.
- Pueden ocurrir casos de neuropatías periféricas, daños en los nervios, deficiencia circulatoria y formaciones óseas heterotópicas.
- Ciertas complicaciones graves pueden asociarse con cualquier tipo de cirugía de reemplazo total de la articulación. Entre estas complicaciones figuran: trastornos genitourinarios, trastornos gastrointestinales, trastornos vasculares, como trombos; trastornos bronquiopulmonares, como embolias; infartos de miocardio o la muerte.
- Ha ocurrido desgaste de los componentes de polietileno y se han publicado informes asociando su ocurrencia con reabsorción ósea, aflojamiento e infección.
- Se han comprobado casos de reacciones de sensibilidad al metal después de reemplazar una articulación.
- Los efectos adversos pueden hacer necesaria una nueva operación, revisión, artrodesis de la articulación involucrada y/o amputación de la extremidad.
- El desequilibrio y/o el relajamiento de los tejidos blandos se ha relacionado con una falta de alineación del componente, que puede dar lugar a desgaste precoz y/o fracaso del implante.
- Con todos los dispositivos de implante, puede producirse la reabsorción ósea progresiva (osteólisis) localizada y asintomática, alrededor de los componentes protésicos, como consecuencia de la reacción de cuerpo extraño a las partículas de cemento, metal, polietileno de peso molecular ultra alto (UHMWPE por sus siglas en inglés) o cerámica. Las partículas se generan por interacción entre los componentes, así como entre los componentes y el hueso, principalmente por medio de los mecanismos de desgaste de adhesión, abrasión y fatiga. En segundo lugar, las partículas también pueden generarse por el desgaste de un tercer cuerpo. La osteólisis puede producir complicaciones futuras, incluyendo el aflojamiento, que requerirán que se retiren y reemplacen los componentes protésicos.
- Se sabe que durante el uso normal y con el transcurso del tiempo, se pueden desprender partículas muy pequeñas de los componentes de metal y polietileno. Aunque la mayor parte de estos desechos

permanecen en la articulación pertinente (es decir, contenidos en la membrana sinovial) o son atrapados por el tejido cicatrizal circundante, es posible que las partículas microscópicas migren fuera de la articulación a diversas partes del cuerpo. Actualmente existen interrogantes no resueltos acerca de los desechos y partículas microscópicas que pueden ser generados a partir de tales componentes. Se ha demostrado que las partículas microscópicas de desecho pueden diseminarse (migrar) por todo el cuerpo y, ocasionalmente, se han descrito como acumulándose en los ganglios linfáticos y otras partes del organismo. Aunque hasta la fecha no se han informado complicaciones médicas significativas como resultado de estas partículas, su desplazamiento o acumulación en el cuerpo han sido descritos en la literatura. Dado el intervalo insuficiente de vigilancia a que se han sometido los pacientes con estos dispositivos, y el hecho de que estos últimos se están usando actualmente en pacientes más jóvenes, permaneciendo en el cuerpo por intervalos progresivamente más prolongados, se debe declarar que los efectos a largo plazo de estas partículas, en caso de ocurrir, son desconocidos. Los efectos a largo plazo que pueden, teóricamente, ocurrir incluyen:

- **Cáncer:** Actualmente no se cuenta con evidencia científica para vincular los desechos metálicos o de polietileno con el cáncer. Sin embargo, la posibilidad no puede descartarse.
- **Linfadenopatía y acumulación en otros tejidos/órganos:** Hubo algunos informes sobre la acumulación de desechos del desgaste en los ganglios linfáticos (próximos y distantes). Aunque no se han informado complicaciones médicas ni procesos patológicos como resultado de estas acumulaciones, su existencia debe tenerse en cuenta para facilitar el diagnóstico y evitar la confusión con lesiones sospechosas, de tipo canceroso o de otros tipos.
- **Enfermedad sistémica:** Se ha especulado que podría haber una asociación entre la migración de desechos y efectos sistémicos que hasta este momento no han sido especificados. Es posible que en algún momento del futuro se pueda demostrar un cierto efecto a largo plazo. Sin embargo, como se cuenta con datos científicos muy escasos que sugieran una asociación entre la migración de desechos y la enfermedad sistémica, se considera que los beneficios de estos dispositivos son claramente superiores a los riesgos potenciales de cualquier efecto teórico a largo plazo.

Interacción con la obtención de imágenes por resonancia magnética

El Sistema Rotuliano Triathlon no ha sido evaluado en cuanto a seguridad y compatibilidad en el ambiente de RM. El Sistema Rotuliano Triathlon no ha sido sometido a pruebas de calentamiento o migración en el ambiente de RM.

Esterilización

- Este componente rotuliano total ha sido esterilizado por radiación gamma o plasma de gas de peróxido de hidrógeno. Consulte la etiqueta del empaque para el método de esterilización.
- El empaque de todos los productos estériles debe examinarse buscando fallas en la barrera estéril antes de abrirlo. En caso de encontrarse fallas, se debe considerar que el producto no es estéril. Se dispone de prótesis de ensayo especiales para evitar tener que abrir cualquier aspecto del empaque estéril antes de usar el componente.
- Se debe tratar de impedir la contaminación del componente. En caso de contaminación, este producto debe ser desechado.
- Si el empaque se abre pero el producto no se usa, el componente no debe volver a esterilizarse y debe desecharse o devolverse al abastecedor.
- El dispositivo no debe usarse después de la fecha de vencimiento exhibida en la etiqueta, ya que el empaque no ha sido validado más allá de dicha fecha.
- Los dispositivos de un solo uso no deben ser extraídos y reimplantarse posteriormente, ya que las fuerzas físicas ejercidas por estas acciones pueden comprometer la integridad física, las dimensiones y/o las terminaciones superficiales de los dispositivos. Además, la esterilidad no puede asegurarse en el caso de dispositivos vueltos a usar, ya que los procedimientos de limpieza y repetición de la esterilización no han sido verificados.

PRECAUCIÓN: **LAS LEYES FEDERALES (EE. UU.) LIMITAN LA VENTA DE ESTE DISPOSITIVO A MÉDICOS CON LICENCIA O A PERSONAS QUE DISPONGAN DE UNA AUTORIZACIÓN DE LOS MISMOS.**

ADVERTENCIA: Los componentes rotulados "Para uso cementado solamente" deben implantarse solamente con cemento óseo.

Consulte la etiqueta del producto sobre la situación de la marca CE y del fabricante legal. La marca CE sólo es válida si se encuentra también en la etiqueta del producto.

La tabla siguiente contiene una lista de abreviaturas usadas en las etiquetas de productos de Howmedica Osteonics Corp. :

Término	Abreviatura	Término	Abreviatura
Código alfa	ALPH CDE	Cuello	NK
Ángulo	ANG	Desplazamiento	OFFST
Grado	DEG or °	Diámetro exterior	OD
Diámetro	DIA	Derecho	RT ▶
Extra profundo	XDP	Orificios para tornillos	SCR HLS
Extra grande	XLGE	Lado	SDE
Extra pequeño	XSM	Tamaño	SZE
Cabeza	HD	Pequeño	SM
Altura	HT	Estándar	STD
Diámetro interior	ID	Cono	TPR
Inserto	INSR	Grosor	THKNS
Grande	LGE	Tipo	TYP
Izquierdo	◀ LFT	Con	W/
Longitud	LNTH	Sin	W/O
Medio	MED		

Português

FOLHETO INFORMATIVO DO JOELHO TOTAL TRITANIUM TRIATHLON DA HOWMEDICA OSTEONICS

Descrição

Os sistemas de joelho total da Howmedica Osteonics Corp. incluem a Placa de base Tritanium Triathlon que foi concebida para ser utilizada com os componentes femorais do sistema de Joelho Primário Triathlon, insersores tibiais e componentes patelares para substituição reconstrutiva total da articulação do joelho. As características específicas de cada dispositivo encontram-se descritas na etiqueta do produto. A Placa de base Tritanium Triathlon está indicada para aplicações com e sem cimento.

Componentes femorais: A Placa de base Tritanium Triathlon é compatível com os modelos de fixação (LC) e sacrifício (de estabilização posterior - PS) dos ligamentos cruzados Triathlon.

Componentes tibiais: A Placa de base Tritanium Triathlon é compatível com insersores tibiais Triathlon em modelos de fixação (LC) dos ligamentos cruzados, estabilização posterior (PS) e estabilização condiliana (CS). Os insersores tibiais estão disponíveis numa variedade de espessuras e vários graus de restrição.

Nota: A Placa de base Tritanium Triathlon é embalada em conjunto com uma Almofada do impactador. A Almofada do impactador só se destina a ser utilizada durante o passo de impactação da placa de base tibial e deve ser descartada depois de concluída a impactação. A Almofada do impactador não se destina a implantação.

Componentes patelares: Os componentes de recobrimento patelar estão disponíveis em modelos de material plástico simétrico e assimétrico e com reforço metálico. A utilização de um componente patelar é opcional. A Placa de base Tritanium Triathlon é compatível com todos os componentes patelares Triathlon.

Materiais

• Liga de crómio e cobalto ASTM F-75	Componentes femorais
• Liga de crómio e cobalto ASTM F-90	Arame de travagem para insersores tibiais
• Liga de crómio e cobalto ASTM F-1537	Cavilhas femorais
• Liga de titânio ASTM F-136	Componentes tibiais
• Titânio CP ASTM F-67	Componentes tibiais
• Fosfato de cálcio ASTM F-1185	Componentes femorais, componentes patelares
• Polietileno de ultra alto peso molecular ASTM F-648	Insersores de apoio tibial, componentes patelares

Indicações

Indicações gerais para a artroplastia total do joelho (TKR):

- Doença dolorosa e incapacitante da articulação do joelho causada por: doença não inflamatória degenerativa das articulações (incluindo osteoartrite, artrite traumática ou necrose avascular), artrite reumatóide ou artrite pós-traumática.
- Perda pós-traumática da configuração e da função da articulação do joelho.
- Deformações varus/valgus moderadas ou de flexão, nas quais as estruturas ligamentosas podem recuperar uma função e estabilidade adequadas.
- Revisão de fracassos anteriores de próteses de joelho ou de outras intervenções.
- Fractura do fémur distal e/ou da tíbia proximal que não passíveis de estabilização por técnicas padrão de tratamento de fracturas.

A Placa de base Tritanium Triathlon está indicada para utilização com e sem cimento.

Indicações adicionais para os componentes de estabilização posterior (PS):

- Instabilidade ligamentosa que requer geometrias de superfície de apoio do implante com mais restrição.
- Carência ou deficiência do ligamento cruzado posterior.
- Grave instabilidade antero-posterior da articulação do joelho.

Contra-indicações

- Qualquer infecção activa ou suspeita de infecção latente na articulação do joelho ou em tecidos adjacentes.
- Focos de infecção afastados, que podem causar uma propagação hematogénica ao nível do local do implante.
- Qualquer perturbação mental ou neuromuscular susceptível de causar um risco inaceitável de instabilidade da prótese, perda da fixação da prótese ou complicações durante os cuidados pós-operatórios.
- Massa óssea comprometida por doença, infecção ou implantação prévia, que não possa proporcionar um apoio e/ou fixação adequados da prótese.
- Imaturidade esquelética.
- Grave instabilidade da articulação do joelho devido a falta de integridade e função do ligamento colateral.
- Obesidade. Os doentes obesos ou com excesso de peso podem submeter a prótese a cargas que podem ocasionar a perda da fixação do dispositivo ou a falha do próprio dispositivo.

Precauções

- Os cirurgiões devem informar os doentes sobre os limites da reconstrução e sobre a necessidade de proteger o implante contra a carga do peso total, até que tenham ocorrido a fixação e consolidação adequadas. A actividade excessiva ou um traumatismo que afecte a substituição da articulação, têm sido implicados no insucesso da reconstrução, devido ao afrouxamento, fractura e/ou desgaste dos implantes protésicos. A folga dos componentes pode resultar num aumento das partículas de desgaste, bem como lesões ósseas, tornando o sucesso da cirurgia de revisão mais difícil.
- Os cirurgiões devem aconselhar os doentes a limitar as actividades e a proteger a articulação substituída contra tensões pouco razoáveis, e a cumprir as instruções do médico relativamente aos cuidados e tratamento de acompanhamento.
- Os cirurgiões devem avisar os doentes sobre os possíveis efeitos adversos, incluindo a vida de serviço finita do dispositivo e a necessidade de protecção do implante no pós-operatório. O cirurgião deve avisar os doentes de que o dispositivo não reproduz a flexibilidade, força, fiabilidade nem a durabilidade de uma articulação normal saudável e que o implante se pode quebrar ou danificar em resultado de actividade intensa ou traumatismo.
- A selecção, colocação e fixação adequadas dos componentes de joelho total constituem factores críticos que afectam a vida útil do implante. À semelhança do que acontece a todos os implantes protésicos, a durabilidade destes componentes é afectada por numerosos factores biológicos, biomecânicos e outros factores extrínsecos, que limitam a sua vida útil. Em conformidade, o cumprimento rigoroso das indicações, contra-indicações, precauções e advertências para este produto é essencial para maximizar potencialmente a vida útil.

Utilização e Implante

- Devem usar-se os componentes de ensaio recomendados para determinar o tamanho, a redução do ensaio e fazer uma avaliação da amplitude do movimento, conservando assim a integridade dos implantes definitivos e a esterilidade da sua embalagem.
- Estão disponíveis matrizes radiográficas para ajudar a prognosticar o tamanho e o estilo dos componentes antes da cirurgia.

- Deve proceder-se com cuidado para remover espículas ósseas, fragmentos de cimento ósseo e resíduos metálicos do local de implantação de modo a reduzir o risco de desgaste acelerado das superfícies articulares do implante induzido por resíduos.
- Os protocolos cirúrgicos da Howmedica Osteonics Corp. oferecem informações suplementares sobre os métodos de procedimento.
- Consultar a etiqueta do produto para obter a compatibilidade específica com outros produtos. Em geral, aplicam-se as seguintes regras:
  - Utilize apenas femorais PS com os Apoios Tibiais PS
  - Utilize apenas femorais CR com os Apoios Tibiais CR
  - Utilize femorais PS ou CR com os Apoios Tibiais CS

Informações para os doentes

- O cirurgião deve informar o doente sobre os limites da reconstrução e sobre a necessidade de proteger o implante contra a carga do peso total, até que tenham ocorrido a fixação e consolidação adequadas. A actividade excessiva ou um traumatismo que afecte a substituição da articulação, têm sido implicados no insucesso da reconstrução, devido ao afrouxamento, fractura e (ou) desgaste dos implantes protésicos. A folga dos componentes pode resultar num aumento das partículas de desgaste, bem como lesões ósseas, tornando o sucesso da cirurgia de revisão mais difícil.
- O cirurgião deve aconselhar o doente a limitar as actividades e a proteger a articulação substituída contra tensões pouco razoáveis, e a cumprir as instruções do médico relativamente aos cuidados e tratamento de acompanhamento.
- O cirurgião deve advertir o doente dos riscos cirúrgicos e dos possíveis efeitos adversos. O cirurgião deve avisar o doente para o facto de que o dispositivo não é igual a uma articulação saudável normal e que o implante se pode quebrar ou danificar devido a actividades estrénuas ou a traumatismo, e que o dispositivo tem uma duração limitada e pode ser necessário substituí-lo no futuro.
- A bacteriemia transitória pode ocorrer na vida diária. Também pode estar relacionada com tratamentos dentários, exames endoscópicos, e outras intervenções cirúrgicas menores. Para evitar a infecção no local do implante, talvez seja aconselhável utilizar uma profilaxia antibiótica, antes e depois dessas intervenções.

Advertências

- Elimine todos implantes danificados ou indevidamente manuseados.
- Nunca reutilize qualquer implante, mesmo que pareça não estar danificado.
- Não implante a Almofada do impactador. A Almofada do impactador destina-se a ser usada apenas durante o passo de impactação tibial. Retire e descarte de imediato após o processo de impactação.
- As áreas de suporte polidas não podem entrar em contacto com superfícies rígidas ou abrasivas.
- As áreas de suporte têm de estar sempre limpas e isentas de resíduos antes da desmontagem.
- O contorno ou flexão de um implante podem reduzir a respectiva resistência à fadiga e provocar uma falha sob carga.
- O fio metálico de retenção do componente não deve ser manipulado nem removido, dado que é imprescindível para a segurança da montagem. Eliminar todos os componentes tibiais se o arame metálico de retenção parecer estar danificado ou ter sido manuseado de forma inadequada. A manipulação indevida deste conjunto pode causar o funcionamento inadequado do mecanismo de retenção.
- Deve proceder-se com cuidado para não danificar as luvas cirúrgicas, ao manipular quaisquer dispositivos ortopédicos afiados ou cortantes.
- Excepto onde indicado, a Howmedica Osteonics Corp. recomenda vivamente não usar componentes de joelho total de outros fabricantes com componentes de joelho total da Howmedica Osteonics. Qualquer utilização desse tipo anulará a responsabilidade da Howmedica Osteonics Corp. acerca do desempenho do implante resultante desse conjunto de componentes mistos.

- A Howmedica Osteonics Corp. recomenda vivamente não usar parafusos ósseos de outros fabricantes com os componentes de prótese total de joelho Howmedica Osteonics, devido às variações que existem entre as configurações da cabeça do parafuso e da superfície de apoio do parafuso.
- A extracção intencional de um componente de prótese total de joelho pode obter-se utilizando cuidadosamente rebarbas de corte, osteótomos delgados e estreitos e forças de extracção moderadas.
- A extracção intencional da peça de inserção tibial de plástico depois da sua montagem na placa de base de metal ocasiona a destruição do componente de plástico. Deve proceder-se com cuidado para não amolgar nem entalhar a superfície da placa de base tibial durante a extracção da peça.
- Devolva todas as embalagens com defeitos na protecção de esterilização ao fornecedor. **Não re-esterilizar.**

Efeitos Adversos

- Apesar de a vida útil dos componentes de substituição total do joelho ser difícil de calcular, esta é finita. Estes componentes fabricam-se com materiais estranhos que se colocam no interior do corpo para uma restauração eventual da mobilidade ou redução da dor. No entanto, devido a numerosos factores biológicos, mecânicos e físico-químicos que podem afectar estes dispositivos, mas que não podem avaliar-se *in vivo*, não se pode esperar que os componentes suportem indefinidamente o nível de actividade e as cargas que são suportadas pelos ossos saudáveis normais. Os cirurgiões devem aconselhar os doentes para não alimentarem ilusões irrealistas em relação à vida útil do dispositivo.
- A prótese femoral, tibial ou patelar pode deslocar-se devido a actividades inadequadas do doente, traumatismo ou outras considerações biomecânicas.
- Os componentes totais de joelho podem afrouxar. Pode produzir-se um afrouxamento mecânico prematuro devido a uma fixação inicial inadequada, infecção latente, carga prematura da prótese, alinhamento deficiente dos componentes ou traumatismo. Pode produzir-se um afrouxamento tardio resultante de traumatismo, infecção, complicações biológicas com inclusão de osteólise ou problemas mecânicos, com a subsequente possibilidade de erosão dos ossos e/ou de dores ósseas.
- Numa pequena percentagem de casos ocorreu fractura devido à utilização dos componentes de prótese total de joelho, entre eles os componentes tibiais, femorais e patelares. A fractura dos componentes do joelho pode ser causada pelo suporte insuficiente do componente pelo osso subjacente ou devido a uma fixação deficiente do componente.
- Podem ocorrer casos de neuropatias periféricas, lesões nevrálgicas, deficiência circulatória e formações ósseas heterotópicas.
- Complicações graves podem associar-se a qualquer tipo de cirurgia de substituição total da articulação. Estas complicações incluem, mas não se limitam a: perturbações génito-urinárias; perturbações gastrintestinais; perturbações vasculares, tais como tromboses; perturbações broncopulmonares, tais como embolias; enfarte de miocárdio ou morte.
- Observaram-se casos de desgaste dos componentes de polietileno e informações documentadas que associam o dito desgaste com a reabsorção, afrouxamento e infecção dos ossos.
- Comprovaram-se casos de sensibilidade ao metal na sequência da substituição de uma articulação.
- Os efeitos adversos podem tornar necessária uma nova operação, revisão, artrodese da articulação em questão e/ou amputação do membro.
- O desequilíbrio e/ou laxidão dos tecidos moles foram relacionados com o alinhamento inadequado dos componentes, o que pode dar origem a um desgaste e/ou falha precoces do implante.
- Com todos os dispositivos de implante, pode produzir-se a reabsorção óssea progressiva (osteólise) localizada e assintomática, em volta dos componentes protésicos, como consequência de reacção a corpos estranhos às partículas de cimento, metal, polietileno de ultra-alto peso molecular (UHMWPE) e/ou cerâmica. As partículas produzem-se por interacção entre os componentes, assim como entre os componentes e o osso, principalmente por meio dos mecanismos de desgaste por adesão, abrasão e fadiga. Em segundo lugar, as partículas também podem produzir-se pelo desgaste de um terceiro corpo. A osteólise pode produzir complicações futuras, incluindo o afrouxamento, necessitando que se retirem e substituam os componentes protésicos.

- Sabe-se que partículas muito pequenas de componentes de metal e de polietileno podem desprender-se dos componentes durante o uso normal e com o tempo. Se bem que a maioria destas partículas permaneçam na articulação relevante (por exemplo, contidas na sinóvia) ou fiquem retidas no tecido fibroso circundante, partículas microscópicas podem possivelmente viajar ou migrar fora da articulação para várias zonas do corpo. Actualmente, existem questões ainda não esclarecidas sobre resíduos e partículas microscópicas que podem ser produzidas a partir destes componentes. Foi mostrado que partículas de resíduos microscópicos podem ser disseminadas (migrar) ao longo do corpo e em determinadas ocasiões têm sido observadas acumulações das mesmas nos nós linfáticos e em outras partes do corpo. Apesar de não terem sido comunicadas até à data complicações médicas graves como consequência das ditas partículas, a sua migração e/ou acumulação no corpo têm sido descritas nos impressos informativos. Considerando o período de tempo insuficiente de acompanhamento de que os doentes portadores destes dispositivos têm beneficiado e o facto de que estes dispositivos estão actualmente a ser utilizados em doentes mais jovens e permanecem no corpo durante períodos de tempo cada vez mais longos, deve referir-se que se desconhecem os efeitos destas partículas a longo prazo, caso estes existam. Os efeitos a longo prazo que têm sido teoricamente referidos incluem:
  - **Cancro:** Actualmente, não existem provas científicas que associem as partículas metálicas ou de polietileno a cancro. No entanto, esta possibilidade não pode ser posta de parte.
  - **Linfadenopatia e acumulação em outros tecidos/órgãos:** Têm sido apresentados alguns relatórios sobre a acumulação de partículas provenientes de desgaste nos nós linfáticos (próximo e distal). Se bem que não tenham sido comunicadas complicações médicas nem doenças provocadas por estas acumulações, a sua existência deverá ser reconhecida para facilitar o diagnóstico e evitar a confusão com lesões suspeitas, cancerosas ou de outro tipo.
  - **Afecções sistémicas:** Têm sido feitas algumas conjecturas sobre o facto de que poderia existir uma associação entre a migração de partículas e efeitos sistémicos ainda não especificados. É possível que alguns efeitos a longo prazo possam ser demonstrados futuramente em determinada altura, mas dado que existe um número ínfimo de dados científicos sugerindo a associação entre a migração de partículas e afecções sistémicas, crê-se que os benefícios destes dispositivos ultrapassam os possíveis riscos de qualquer efeito teórico a longo prazo.

Interacção com Ressonância Magnética Nuclear

O sistema de Joelho Triathlon não foi avaliado, em termos de segurança e compatibilidade, no ambiente de RM. O Sistema de Joelho Triathlon não foi testado em termos de aquecimento ou migração no ambiente de RM.

Esterilização

- Este componente de joelho total foi esterilizado por radiação gama ou plasma de peróxido de hidrogénio. Consulte o folheto informativo para o método de esterilização.
- Devem inspeccionar-se as embalagens de todos os produtos esterilizados para ver se apresentam defeitos na barreira asséptica antes da sua abertura. No caso da existência de um defeito deste tipo, deve considerar-se que o produto não está esterilizado. Estão disponíveis próteses de ensaio especiais, a fim de evitar a abertura da embalagem esterilizada, antes da utilização do componente.
- Deve proceder-se com cuidado para impedir a contaminação do componente. Em caso de contaminação, deverá eliminar-se este produto.
- Se a embalagem for aberta, mas o produto não for utilizado, o componente não deverá voltar a esterilizar-se. Deverá ser eliminado ou devolvido ao fornecedor.
- O dispositivo não deve ser usado depois do prazo de validade que consta da etiqueta, dado que o processo de embalagem não foi validado depois desta data.
- Dispositivos de uso único não podem ser explantados e subsequentemente reimplantados, dado que as forças físicas exercidas em consequência destas acções podem comprometer a integridade física, dimensões e/ou acabamentos de superfície dos dispositivos. Para além disso, não é possível garantir a esterilidade para dispositivos reutilizados, dado que os procedimentos de limpeza e re-esterilização não estão confirmados.

ATENÇÃO: **NOS TERMOS DA LEI FEDERAL (EUA), A VENDA DESTE DISPOSITIVO ESTÁ SUJEITA A PRESCRIÇÃO MÉDICA.**

ADVERTÊNCIA: Os componentes rotulados “Apenas Para Utilização Cimentada” destinam-se a ser implantados apenas com cimento ósseo.

A Stryker Corporation ou as suas divisões ou outras entidades institucionais associadas detêm, utilizam ou solicitaram o registo das seguintes marcas comerciais: Howmedica, Osteonics, Stryker, Triathlon. Todas as outras marcas registadas ou marcas de serviço são marcas registadas ou marcas de serviço dos respectivos proprietários ou detentores.

Consulte o rótulo do produto para o Estado da Marca CE e Fabricante Legal. A marca CE só é válida se também estiver impressa no rótulo do produto.

No próximo quadro apresenta-se uma lista das abreviaturas que são utilizadas na rotulagem dos produtos da Howmedica Osteonics Corp. :

Termo	Abreviatura	Termo	Abreviatura
Código Alfa	ALPH CDE	Colo	NK
Ângulo	ANG	Compensação	OFFST
Grau	DEG or °	Diâmetro externo	OD
Diâmetro	DIA	Direita	RT ▶
Extra Profundo	XDP	Orifícios para parafusos	SCR HLS
Extra Grande	XLGE	Lado	SDE
Extra Pequeno	XSM	Tamanho	SZE
Cabeça	HD	Pequeno	SM
Altura	HT	Padrão	STD
Diâmetro Interno	ID	Cónico	TPR
Insersor	INSR	Espessura	THKNS
Grande	LGE	Tipo	TYP
Esquerda	◀ LFT	Com	W/
Comprimento	LNTH	Sem	W/O
Médio	MED		

Svenska

HOWMEDICA OSTEONICS TRIATHLON TRITANIUM TOTAL KNEE TOTALKNÄLEDSPLASTIK — BRUKSANVISNING

Beskrivning

I Howmedica Osteonics Corp.'s totala knäsystem ingår Triathlon Tritanium Baseplate basplattan för användning med Triathlon Primary Knee systemets femorala komponenter, tibiala insatser och patellära komponenter för att erhålla total rekonstruktiv knäledsplastik. De egenskaper som är specifika för varje komponent anges på förpackningspåskriften. Triathlon Tritanium basplattan är indicerad för både cementfria och cementerade applikationer.

Femorala komponenter: Triathlon Tritanium basplattan är kompatibel med Triathlon korsbandssparande (cruciate retaining - CR) och korsbandsoffrande posteriort stabiliserade (posteriorly stabilized – PS) modeller.

Tibiala komponenter: Triathlon Tritanium basplattan är kompatibel med tibiala Triathlon insatser i korsbandssparande (cruciate retaining - CR), posteriort stabiliserade (posteriorly stabilized – PS) och kondylärt stabiliserande (condylar stabilizing - CS) modeller. Tibiala insatser finns i olika tjocklekar och med olika restriktioner:

Obs! Ett impaktorblock finns med i förpackningen för Triathlon Tritanium basplattan. Impaktorblocket används endast under impaktion av den tibiala basplattan och måste kasseras efter att impaktionen har slutförts. Impaktorblocket är inte avsett för implantation.

Patellära komponenter: Patellära ombeläggningskomponenter finns i helsymmetriska och osymmetriska modeller av helplast samt med modeller med baksida av metall. Användning av patellära komponenter är valfri. Triathlon Tritanium basplattan är kompatibel med alla patellära Triathlon komponenter.

Material

• ASTM F-75 koboltkromlegering	Femorala komponenter
• ASTM F-90 koboltkromlegering	Låstråd för tibial insats
• ASTM F-1537 koboltkromlegering	Femorala sprinter
• ASTM F-136 titanlegering	Tibiala komponenter
• ASTM F-67 CP titan	Tibiala komponenter
• ASTM F-1185 kalciumfosfat	Femorala komponenter, patellära komponenter
• ASTM F-648 polyeten med ultrahög molekylvikt (UHMWPE)	Tibiala lagerinsatser, patellära komponenter

Indikationer

Generella indikationer för totala knäledsartroplastiker:

- plågsam, rörelsehämmande ledsjukdom i knät på grund av: icke-inflammatorisk degenerativ ledsjukdom, bl.a. osteoartrit och avaskulär nekros, reumatoid artrit och posttraumatisk artrit.
- posttraumatisk förlust av knäledens konfiguration och funktion.
- moderat varus-, valgus-, eller flexionsdeformitet varvid ligamentstrukturerna återföras till adekvat funktion och stabilitetkan.
- revision av tidigare misslyckad knäledsplastik eller annat ingrepp.
- fraktur av distala femur och/eller proximala tibia som inte kan stabiliseras med standardtekniker för behandling av frakturer.

Triathlon Tritanium basplattan är indicerad för både cementfria och cementerade applikationer.

Ytterligare indikationer för posteriort stabiliserade (PS) komponenter:

- ligamentinstabilitet som kräver implantat med lagerytor vars geometri ger ökad restriktion.
- avsaknad av, eller ej fungerande bakre korsband.
- svår anteroposterior instabilitet av knäleden.

Kontraindikationer

- aktiv eller misstänkt latent infektion i eller omkring knäleden.
- infektionshärdar på andra ställen vilka kan medföra hematogen spridning till implantationsstället.
- mental eller neuromuskulär sjukdom vilket medför en oacceptabel risk för protesinstabilitet, misslyckad protesfixering eller komplikationer under postoperativ vård.
- benmassan är kompromitterad till följd av sjukdom, infektion eller tidigare implantation som inte ger protesen tillräckligt stöd och/eller fixering.
- skelettomogenhet.
- svår instabilitet i knäleden, sekundärt till utebliven integritet och funktion av kollateralligamenten.
- Fetma. En överviktig patient eller en patient som lider av fetma kan belasta protesen på sådant sätt att det leder till att produkten inte kan fixeras eller till produkthaveri.

Försiktighetsåtgärder

- Kirurgen måste informera patienten om protesens begränsningar samt om behovet av att skydda implantatet från full belastning tills adekvat fixering och läkning har skett. Omättlig aktivitet eller trauma som påverkar ledprotesen har utpekats som orsak till protesens haveri, till följd av lossning, fraktur och/eller nedslitning av protesimplantaten. Om komponenterna lossnar kan följden bli ökad produktion av nedslitningspartiklar, samt skada på skelettet, varvid en framgångsrik revision blir svårare att uppnå.
- Kirurgen måste förmana patienten att begränsa sin aktivitetsnivå och att skydda ledprotesen från onödiga påfrestningar, samt att iaktta läkarens anvisningar beträffande uppföljande vård och behandling.
- Kirurgen bör varna patienten för möjliga skadliga effekter samt att implantatet har begränsad livslängd och behovet av att skydda den efter operationen. Kirurgen bör varna patienten för att produkten inte är lika flexibel, stark, pålitlig och slitstark som en normal frisk led, att implantatet kan gå sönder eller skadas till följd av påfrestande aktivitet eller trauma.
- Lämpligt val, placering och fixering av de totala knäledskomponenterna utgör avgörande faktorer som påverkar implantatets funktionella livslängd. I likhet med alla protesimplantat, påverkas varaktigheten av dessa komponenter av flera biologiska, biomekaniska och andra yttre faktorer som begränsar protesens funktionella livslängd. Därför är det synnerligen viktigt att strikt följa de indikationer, kontraindikationer, försiktighetsåtgärder och varningar som gäller denna produkt för att implantatet skall vara funktionsdugligt så länge som möjligt.

Användning och implantation

- Rekommenderade försökskomponenter ska användas vid storleksbestämning, försöksreducering samt vid försök att utvärdera rörelseomfånget. Både implantaten och deras sterila förpackningar bevaras på så vis intakta.
- Röntgenmallar finns för att underlätta preoperativ förutsägelse av komponentstorlek och form.
- Det är viktigt att rengöra implantationsområdet från benflisor, bencementsfragment och metallskräp för att minska risken av accelererad nedslitning av implantatets ledytor.
- Howmedica Osteonics Corp.'s operationsprotokoll ger ytterligare metodinformation.
- Läs förpackningspåskriften för specifik kompatibilitet med andra produkter. I allmänhet gäller det följande:
  - Använd femorala PS komponenter endast med tibiala PS lagerinsatser.
  - Använd femorala CR komponenter endast med tibiala CR lagerinsatser.
  - Använd antigen femorala PS eller CR komponenter med tibiala CS lagerinsatser.

Patientinformation.

- Kirurgen måste informera patienten om protesens begränsningar samt om behovet av att skydda implantatet från full belastning innan adekvat fixering och läkning har skett. Omättlig aktivitet eller trauma som påverkar ledprotesen har utpekats som orsak till protesens haveri, till följd av lossning, fraktur och/eller nedslitning av protesimplantaten. Om komponenterna lossnar kan följden bli ökad produktion av nedslitningspartiklar, samt skada på skelettet, varvid en framgångsrik revision blir svårare att uppnå.
- Kirurgen måste förmana patienten att begränsa sin aktivitetsnivå och att skydda ledprotesen från onödiga påfrestningar, samt att iaktta läkarens anvisningar beträffande uppföljande vård och behandling.
- Kirurgen bör varna patienten beträffande operationsriskerna och eventuella biverkningar. Kirurgen måste varna patienten för att produkten inte är likvärdig med en normal, frisk led, att implantatet kan gå sönder eller skadas till följd av påfrestande aktivitet eller trauma samt att implantatet har begränsad livslängd och kan behöva bytas ut i framtiden.
- Övergående bakteremi kan uppstå i det dagliga livet. Tandvård, endoskopiska undersökningar och andra mindre kirurgiska ingrepp har också förknippats med övergående bakteremi. För att förebygga infektion vid implantationsstället kan profylaktisk användning av antibiotika före och efter ingreppet vara att rekommendera.

Varningar

- Kassera alla skadade eller felaktigt hanterade implantat.
- Återanvänd aldrig ett implantat, även om det förefaller vara oskadat.
- Implantera inte impaktorblocket. Impaktorblocket används endast under det tibiala impakteringsskedet. Ta bort och kassera omedelbart efter impakteringen.
- Polerade lagerytor får inte komma i kontakt med hårda eller skrovliga ytor.
- Lagerytorna måste alltid vara rena och fria från skräp innan de monteras.
- Formning eller böjning av ett implantat kan minska dess förmåga att motstå materialtrötthet och medföra funktionsfel under belastning.
- Låstråden av metall på insatsen får inte hanteras eller avlägsnas, eftersom den är absolut avgörande för montagets säkerhet. Om låstråden av metall förefaller vara skadad eller felaktigt hanterad, skall den tibiala insatsen kastas. Manipulering av detta montage kan orsaka funktionsfel i fasthållningsmekanismen.
- Var försiktig så att det inte går hål på operationshandskarna vid hantering av ortopediska instrument med vassa kanter.
- Howmedica Osteonics Corp. avråder eftertryckligen från användning av totala knäledskomponenter från andra tillverkare tillsammans med Howmedica Osteonics totala knäledsplastikkomponenter. Allt sådant bruk medför att Howmedica Osteonics Corp.´s ansvar beträffande funktionen hos ett sådant implantat med blandade komponenter upphävs.
- Howmedica Osteonics Corp. avråder eftertryckligen från användning av benskruvar från andra tillverkare, tillsammans med Howmedica Osteonics totala knäledskomponenter på grund av de olikheter som finns mellan skruvhuvud- och skruvsäteskonfigurationer.
- Avsiktligt avlägsnande av en total knäledskomponent kan ske med hjälp av försiktig användning av skärborr, tunna och smala osteotom samt varsam extraktion.
- Avsiktligt avlägsnande av den tibiala plastinsatsen efter det att den har monterats i basplattan av metall kommer att medföra att insatsen förstörs. Var noga med att inte orsaka hack eller repor i den tibiala brickans yta, när insatsen avlägsnas.
- Returnera till leverantören alla förpackningar med brister i den sterila barriären. **Får inte omsteriliseras.**

Biverkningar

- Det är visserligen svårt att förutsäga den väntade livstiden på komponenter i totala knäledsplastiker men den är dock begränsad. Dessa komponenter har tillverkats av främmande material som placeras inuti kroppen för att eventuellt återställa rörligheten eller reducera smärta. På grund av de många biologiska, mekaniska och fysikalisk-mekaniska faktorer som påverkar implantaten men som inte kan utvärderas *in*

vivo, kan man emellertid inte förvänta sig att de på obestämd tid skall kunna motstå samma aktivitetsnivå och belastning som normalt friskt ben. Kirurgen bör informera patienterna om att de inte bör hysa orealistiska förväntningar vad beträffar livstiden på produkten.

- Luxation av den femorala, tibiala eller patellara protesen kan förekomma till följd av patientens olämpliga aktiviteter, trauma eller andra biomekaniska orsaker.
- Totala knäledsplastikkomponenter kan lossna. För tidig mekanisk lossning kan förekomma till följd av otillräcklig initial fixering, latent infektion, prematur belastning av protesen, felaktig komponentinriktning eller trauma. Sen lossning kan orsakas av trauma, infektion, biologiska komplikationer, inklusive osteolys, eller mekaniska problem, med efterföljande risk för benerosion och/eller smärta.
- Fraktur till följd av materialtrötthet har förekommit i ett litet antal fall på komponenter i totala knäledsplastiker, inklusive tibiala, femorala och patellara komponenter. Fraktur av en knäledskomponent kan uppstå till följd av otillräckligt stöd för komponenten av det underliggande benet eller på grund av dålig komponentfixering.
- Perifera neuropatier, nervskador, inhiberad blodcirkulation samt heterotop benbildning kan förekomma.
- Allvarliga komplikationer kan förknippas med alla totala ledplastiker. Följande komplikationer kan bl.a. förekomma: genitourinära störningar, gastrointestinala störningar, kärlsjukdomar, inklusive trombos; bronkopulmonella störningar, inklusive emboli; hjärtinfarkt eller dödsfall.
- Nedslitning av polyetenkomponenterna har förekommit och rapporter i litteraturen har förknippat detta med benresorption, lossning och infektion.
- Reaktioner mot metall har rapporterats efter ledplastik.
- Biverkningar kan medföra behov av ny operation, revision, steloperation av den aktuella leden, och/eller amputation av benet.
- Imbalans av mjukdelar och/eller laxitet har anknutits med missriktning av komponenter vilket kan resultera i tidig nedslitning och/eller haveri av implantatet.
- I likhet med alla implanterade produkter kan symtomfri lokaliserad progressiv benresorption (osteolys) uppstå runt proteskomponenterna som en direkt följd av en reaktion mot främmande kropp, och närmare bestämt mot det partikelämne som finns i cement, polyeten av ultrahög molekylvikt (UHMWPE) och/eller keramik. Partiklar uppstår genom interaktion mellan komponenter inbördes såväl som mellan komponenter och ben, huvudsakligen genom materialnedbrytning vid adhesion, slipverkan och materialtrötthet. I andra hand kan partiklar genereras av nedslitning av en främmande kropp. Osteolys kan leda till framtida komplikationer, bland annat lossning, vilket medför att proteskomponenterna måste avlägsnas och bytas ut.
- Mycket små partiklar från metall- och polyetenkomponenter kan fällas ut från komponenterna vid normal användning med tiden. Visserligen stannar huvuddelen av partiklarna kvar i den aktuella leden (m.a.o. förblir i synovium) eller fångas in av omgivande ärrvävnad, men mikroskopiska partiklar kan dock spridas (migrera) utanför leden till andra kroppsdelar. Just nu finns det obesvarade frågor gällande skräp och mikroskopiska partiklar som dessa komponenter kan orsaka. Det har visats att mikroskopiska partiklar kan spridas (migrera) genom hela kroppen och har ibland beskrivits som en ansamling i lymfkörtlar och andra kroppsdelar. Visserligen har inga betydande medicinska komplikationer rapporterats till följd av dessa partiklar, men deras migration och/eller ansamling i kroppen har dock beskrivits i litteraturen. Med hänsyn till den otillräckliga tidsperiod som patienter med dessa produkter har följts, samt det faktum att produkterna för närvarande används på yngre patienter och förblir i kroppen under längre tid, bör man dock påpeka att eventuella långsiktiga effekter av dessa partiklar är okända. De långsiktiga effekter över vilka man spekulerat är bland andra:
  - **Cancer:** Det finns för närvarande inga vetenskapliga belägg för någon koppling mellan metall- eller polyetenrester och cancer. Risken kan dock inte uteslutas.
  - **Lymfadenopati och ansamling i andra vävnader/organ:** Det har funnits några rapporter om ansamling av nedslitningsrester i lymfkörtlarna (proximala och distala). Medicinska komplikationer eller snabbare sjukdomsframskridande har dock inte rapporterats som orsakade av dessa ansamlingar; deras existens skall dock noteras för att underlätta diagnos och för att förhindra sammanblandning med misstänkta lesioner, av cancerart eller annorledes.
  - **Systemisk sjukdom:** En del spekulation har uppstått om det finns något samband mellan migration av produktpartiklar och ännu oidentifierade systemiska effekter. Det är möjligt att

långtidseffekter kan påvisas någon gång i framtiden. Eftersom det finns mycket få vetenskapliga belägg för samband mellan migration av partiklar och systemisk sjukdom, är man dock av den åsikten att fördelarna med dessa produkter klart uppväger de potentiella riskerna för några sådana teoretiska långtidseffekter.

Interaktion med magnetröntgen

Säkerheten och kompatibiliteten hos Triathlon Knee knäledssystem i magnetröntgenmiljö har inte utvärderats. Triathlon Knee knäledssystemets möjliga upphettning och migration i magnetröntgenmiljö har inte utvärderats.

Sterilisering

- Denna knäledskomponent har steriliserats med gammastrålning eller väteperoxidgasplasma. Steriliseringsmetoden är beskriven på förpackningspåskriften.
- Innan förpackningarna av alla sterila komponenter öppnas ska de inspekteras för skador på den sterila barriären. Om sådana skador förekommer måste produkten antas vara icke-steril. Särskilda försöksproteser finns tillgängliga för att undvika behovet att öppna en sterilförpackning innan komponenten ska användas.
- Se till att komponenten inte kontamineras. Om denna produkt kontamineras ska den kasseras.
- Om förpackningen öppnas utan att produkten används, får komponenten inte omsteriliseras och den ska kasseras eller skickas tillbaka till leverantören.
- Produkten får inte användas efter utgångsdatum som visas på förpackningspåskriften då förpackningen inte validerats efter detta datum.
- Engångskomponenter får inte avlägsnas och därefter implanteras på nytt då dessa åtgärder kan leda till att dessa komponenter och/eller ytan skadas och dimensionerna ändras. Steriliteten hos produkter som använts på nytt kan inte säkras då steriliteten efter rengöring och resterilisering inte har verifierats.

VARNING: **ENLIGT FEDERAL LAGSTIFTNING (USA) FÅR DENNA PRODUKT ENDAST SÄLJAS AV LEGITIMERAD LÄKARE ELLER PÅ LEGITIMERAD LÄKARES ORDINATION.**

VARNING: Komponenter som märkts med texten "Cemented Use Only" får implanteras endast med bencement.

Information om status för CE-märket och den lagliga tillverkaren ingår i förpackningspåskriften. CE-märket är giltigt endast om den ingår i förpackningspåskriften.

Följande tabell är en lista på förkortningar som används på Howmedica Osteonics Corp. förpackningspåskrifter:

Namn	Förkortning	Namn	Förkortning
Alfakod	ALPH CDE	Hals	NK
Vinkel	ANG	Förskjutning	OFFST
Grad	DEG or °	Ytterdiameter	OD
Diameter	DIA	Höger	RT ▶
Extra djup	XDP	Skruvhål	SCR HLS
Extra stor	XLGE	Sida	SDE
Extra liten	XSM	Storlek	SZE
Huvud	HD	Liten	SM
Höjd	HT	Standard	STD
Innerdiameter	ID	Kona	TPR
Insats	INSR	Tjocklek	THKNS
Stor	LGE	Typ	TYP
Vänster	◀ LFT	Med	W/
Längd	LNTH	Utan	W/O
Medium	MED		

Suomi

HOWMEDICA OSTEONICSIN TRIATHLON TRITANIUM -POLVEN KOKOTEKONIVELEN KÄYTTÖOHJEET

Kuvaus

Howmedica Osteonics Corp. polven kokotekoniveljärjestelmiin sisältyy Triathlon Tritanium Baseplate -kantalevy, joka on tarkoitettu käytettäväksi Triathlon Primary Knee -polviniveljärjestelmän femoraalisten komponenttien, tibiaalisten sisäkkeiden ja patellaaristen komponenttien kanssa aikaansaamaan polven kokotekonivel. Kunkin tuotteen ominaisuudet on kuvattu tuotteen etiketissä. Triathlon Tritanium -kantalevyä käytetään sekä sementöitävissä että sementittömissä sovelluksissa.

Femoraaliset komponentit: Triathlon Tritanium -kantalevy on yhteensopiva Triathlon- ristisiteet säilyttävien (CR = cruciate retaining) ja ristisiteet uhraavien (posteriorly stabilized -PS) mallien kanssa.

Tibiaaliset komponentit: Triathlon Tritanium -kantalevy on yhteensopiva Triathlon-tibiaalisisäkkeiden ristisiteet säilyttävien (CR = cruciate retaining), posteriorisesti stabiloitujen (PS) ja kondylaarisesti stabiloivien (CS) mallien kanssa. Tibiaalisia sisäkkeitä on saatavana eri paksuisina ja liikelaajuutta enemmän tai vähemmän rajoittavina.

Huomautus: Triathlon Tritanium -kantalevyn pakkaukseen sisältyy Impactor Pad -impaktointialusta. Impaktointialustaa käytetään vain tibiaalisen kantalevyn impaktointivaiheessa, ja se on hävitettävä impaktoinnin jälkeen. Impaktointialustaa ei ole tarkoitettu istutettavaksi.

Patellaariset komponentit: Polvilumpion pinnoitusosia on saatavana kokomuovisina, symmetrisinä ja epäsymmetrisinä ja metallitaustaisina malleina. Patellaaristen komponenttien käyttö on valinnaista. Triathlon Tritanium -kantalevy on yhteensopiva kaikkien patellaaristen Triathlon-komponenttien kanssa.

Materiaalit

• ASTM F-75 koboltti-kromiseos	Femoraaliset komponentit
• ASTM F-90 koboltti-kromiseos	Tibiaalisisäkkeiden lukituslanka
• ASTM F-1537 koboltti-kromiseos	Femoraaliset tapit
• ASTM F-136 titaaniseos	Tibiaaliset komponentit
• ASTM F-67 CP titaani	Tibiaaliset komponentit
• ASTM F-1185 kalsiumfosfaatti	Femoraaliset komponentit, patellaariset komponentit
• ASTM F-648 -ultrasuurimolekyylipainoinen polyeteeni (UHMWPE).	Tibiaaliset sisäkkeet, patellaariset komponentit

Käyttöaiheet

Polven kokontekonivelkirurgian yleiset aiheet:

- Kivulias, toimintakyvyttömyyttä aiheuttava polvinivelsairaus, jonka syynä on: ei-tulehduksellinen degeneratiivinen nivelsairaus (mm. nivelrikko, traumaattinen artriitti tai avaskulaarinen nekroosi, nivelreuma ja posttraumaattinen artriitti.
- trauman aiheuttama polven rakenteiden vaurioituminen ja toiminnan menetys.
- kohtalainen varus-, valgus- tai fleksiodeformiteetti, jossa ligamenttirakenteiden toiminta ja stabiilius voidaan palauttaa.
- epäonnistuneen polven kokotekonivelleikkauksen jälkeinen revisio tai muu toimenpide.
- distaalisen reisiluun ja/tai proksimaalisen sääriluun murtuma, jota ei voida stabiloida murtumien vakiohoitomenetelmiä käyttäen.

Triathlon Tritanium -kantalevyä käytetään sekä sementöitävissä että sementittömissä sovelluksissa.

Lisää posteriorisesti stabiloitujen (PS) komponenttien käyttöaiheita:

- ligamentti-instabilitetti, jonka vuoksi tarvitaan liikelaajuutta rajoittavia istutteen liukupintoja.
- puuttuva tai toimimaton takaristiside.
- vaikea polvinivelen antero-posteriorinen instabiliteetti.

Vasta-aiheet

- käynnissä olevat tai epäillyt latentit infektiot polvinivelessä tai sen läheisyydessä.
- infektiopesäkkeet, jotka voivat aiheuttaa leviämisen veren välityksellä istutuskohtaan.
- sellaiset mielenterveyden häiriöt tai neuromuskulaariset sairaudet, jotka voisivat lisätä kohtuuttomasti tekonivelen instabiliteetin ja irtoamisen tai postoperatiivisten komplikaatioiden riskiä.
- luuaines on heikentynyt aikaisemman infektion tai aikaisemman istutuksen vuoksi, minkä johdosta se ei pysty antamaan riittävästi tukea tekonivelelle ja/tai sen kiinnittymiselle.
- luuston keskenkasvuisuus.
- polven vaikea instabiilius, joka johtuu kollateraaliligamenttien puutoksista ja toiminnanvajauksesta.
- lihavuus. Ylipainoisella tai lihavalla potilaalla tekonivel voi kuormittua liikaa, mikä voi johtaa tekonivelen löystymiseen, irtoamiseen tai rikkoutumiseen.

Varotoimet

- Kirurgin täytyy kertoa potilaille sekä korjaustoimenpiteeseen liittyvistä rajoituksista että siitä, kuinka tärkeää on, ettei istutetta altisteta täydelle varaukselle ennen kuin se on kiinnittynyt ja parantunut riittävästi. Tekoniveliin kohdistunutta liiallista rasitusta ja vaurioita pidetään syynä niiden rikkoutumiseen ja niiden komponenttien löystymiseen, murtumiin ja/tai kulumiseen. Komponenttien löystyminen voi nopeuttaa kulumishiukkasten muodostumista ja luun vaurioitumista, mikä voi heikentää hyvän hoitotuloksen saavuttamisen mahdollisuutta revisioleikkauksen jälkeen.
- Kirurgin on kehotettava potilaita rajoittamaan aktiviteettejään, välttämään tekoniveleen kohdistuvaa kohtuutonta rasitusta ja noudattamaan lääkärin antamia jatkohoitoa ja seurantaa koskevia ohjeita.
- Kirurgin on varoitettava potilaita mahdollisista haittavaikutuksista mukaan lukien tekonivelen rajallisesta kestosta ja istutteen suojaamisen tärkeydestä leikkauksen jälkeen. Kirurgin on varoitettava potilasta siitä, että tekonivelen joustavuus, lujuus, luotettavuus tai kestävyys ei vastaa normaalia tervettä niveltä; että istute voi rikkoutua tai vaurioitua rasittavan toiminnan tai trauman vaikutuksesta.
- Polven kokotekonivelen komponenttien asianmukainen valinta, asentaminen ja kiinnitys ovat oleellisia, tekonivelen käyttöikään vaikuttavia tekijöitä. Kaikkien tekonivelistutteiden tavoin näidenkin komponenttien kestävyyteen vaikuttavat lukuisat biologiset, biomekaaniset ja muut ulkoiset tekijät jotka rajoittavat komponenttien käyttöikää. Tämän vuoksi on tärkeää noudattaa tarkkaan tämän tuotteen käyttöön liittyviä käyttöaiheita, vasta-aiheita, varotoimia ja varoituksia tuotteen käyttöiän maksimoimiseksi.

Käyttö ja istutus

- Komponenttien koon ja liikelaajuuden määrittämiseen sekä sovituskertojen minimoimiseksi on käytettävä suositeltuja sovituskomponentteja lopullisten istutteiden vaurioitumisen ja steriilien pakkausten avaamisen välttämiseksi.
- Röntgenmallineita on saatavana komponenttien koon ja mallin preoperatiivisen määrittämisen helpottamiseksi.
- Istutuskohdan täydellinen puhdistaminen luulastujen, luusementin kappaleiden ja metallijätteiden poistamiseksi on oleellista istutteen nivelpintojen nopean kulumisen välttämiseksi.
- Howmedica Osteonics Corp. toimenpidemanuaaleissa on lisää toimenpiteisiin liittyviä tietoja.
- Tuotteen pakkausmerkinnöissä on mainittu tuotekohtaista yhteensopivuutta koskevat tiedot. Seuraava ohje pätee useimmissa tapauksissa:
  - Käytä femoraalisia PS-komponentteja vain tibiaalisten PS-liukupintojen kanssa.
  - Käytä femoraalisia CR-komponentteja vain tibiaalisten CR-liukupintojen kanssa.
  - Käytä femoraalisten PS- tai CR-komponenttien kanssa v tibiaalisia CS-liukupintoja.

Tiedottaminen potilaille.

- Kirurgin täytyy kertoa potilaille korjaustoimenpiteeseen liittyvistä rajoituksista ja siitä, kuinka tärkeää on, ettei istutetta saa altistaa täydelle varaukselle ennen kuin se on kiinnittynyt ja parantunut riittävästi. Tekoniveliin kohdistunutta liiallista rasitusta ja vaurioita pidetään syynä niiden rikkoutumiseen ja niiden komponenttien löystymiseen, murtumiin ja/tai kulumiseen. Komponenttien löystyminen voi nopeuttaa kulumishiukkasten muodostumista ja luun vaurioitumista, mikä voi heikentää hyvän hoitotuloksen saavuttamisen mahdollisuutta revisioleikkauksen jälkeen.
- Kirurgin on kehotettava potilaita rajoittamaan aktiviteettejään, välttämään tekoniveleen kohdistuvaa kohtuutonta rasitusta ja noudattamaan lääkärin antamia jatkohoitoa ja seurantaa koskevia ohjeita.
- Kirurgin täytyy varoittaa leikkaukseen liittyvistä riskeistä ja mahdollisista komplikaatioista. Kirurgin on varoitettava potilasta siitä, ettei tekonivel vastaa normaalia tervettä niveltä; että istute voi rikkoutua tai vaurioitua rasittavan toiminnan tai trauman vaikutuksesta; että tekonivelen käyttöikä on rajallinen ja se että voidaan joutua vaihtamaan myöhemmin.
- Tilapäisen bakteremian esiintyminen on mahdollista jokapäiväisessä elämässä. Hampaiden käsittely, tähystystutkimukset ja muut pienet leikkaustoimenpiteet voivat aiheuttaa tilapäisen bakteremian. Istutteen seudun infektioiden estämiseksi voi olla hyödyllistä käyttää antibioottiprofylaksiaa ennen tällaisia toimenpiteitä ja niiden jälkeen.

Varoitukset

- Hävitä kaikki vaurioituneet ja väärin käsitellyt istutteet.
- Istutteita ei saa koskaan käyttää uudelleen, vaikka ne näyttäisivätkin ehjiltä.
- Impaktointialustaa ei saa istuttaa potilaaseen. Impaktointialustaa saa käyttää vain tibiaalisen kantalevyn impaktointivaiheessa. Poista ja hävitä se välittömästi impaktoinnin jälkeen.
- Liukupintojen kiillotetut alueet eivät saa joutua kosketukseen kovien tai hankaavien pintojen kanssa.
- Liukupintojen pitää aina olla puhtaat ja kudosjätteettömät ennen kokoamista.
- Istutteiden muotoilu tai taivuttaminen voi heikentää niiden kestävyyttä ja aiheuttaa niiden rikkoutumisen rasituksen vaikutuksesta.
- Sisäkkeen metallista pidäkelankaa ei saa käsitellä tai poistaa, sillä se on oleellinen kokoonpanon koossa pysymisen kannalta. Hävitä kaikki tibiaaliset liukupintasisäkkeet, jos pidäkelanka on vaurioitunut tai sitä on käsitelty väärin. Tämän kokoonpanon vaurioittaminen voi aiheuttaa pidäkemekanismin toiminnan vaurioitumisen.
- On varottava, etteivät leikkauskäsineet rikkoudu teräviä ortopedisiä välineitä käsiteltäessä.
- Howmedica Osteonics Corp. varoittaa vakavasti käyttämästä muiden valmistajien polven kokotekonivelen komponentteja minkään Howmedica Osteonics polven kokotekonivelen komponentin kanssa. Ohjeiden vastainen käyttö vapauttaa Howmedica Osteonics Corp. vastuusta, joka koskee tällaisen yhdistelmäistutteen toimivuutta.
- Howmedica Osteonics Corp. varoittaa vakavasti käyttämästä muiden valmistajien luuruuveja minkään Howmedica Osteonics polven kokotekonivelen komponentin kanssa ruuvien kantojen ja kantaupotteiden erilaisuuden vuoksi.
- Polven kokotekonivelen komponentit voidaan irrottaa käyttämällä varovasti leikkaavia poria, ohuita ja kapeita osteotomeja ja vetämällä komponentit irti liiallista voimankäyttöä välttäen.
- Muovisen tibiaalisisäkkeen poistaminen sen jälkeen, kun se on kiinnitetty metalliseen kantalevyyn, rikkoo muovisisäkkeen. On varottava raapimasta tai vaurioittamasta tibiaalisen kantalevyn pintaa sisäkkeen poiston yhteydessä.
- Kaikki pakkaukset, joiden steriiliaidake on vaurioitunut, on palautettava tavarantoimittajalle. **Ei saa steriloida uudelleen.**

Haittavaikutukset

- Polven kokotekonivelen komponenttien käyttöikää on vaikea ennustaa, mutta se on kuitenkin rajallinen. Komponentit on valmistettu elimistölle vieraista aineista, jotka asetetaan elimistöön liikkuvuuden palauttamiseksi ja kivun vähentämiseksi. Komponenttien ei kuitenkaan voida odottaa kestävän loputtomasti samanlaista kuormitusta ja rasitusta kuin normaali terve luusto, sillä niihin kohdistuu elimistössä monia sellaisia biologisia, mekaanisia ja fysikaalis-kemiallisia vaikutuksia, joita ei *in vivo* pystytä selvittämään. Kirurgin pitää kertoa potilaalle, ettei tällä saisi olla epärealistisia odotuksia toiminnan suhteen.
- Femoraalinen, tibiaalinen ja patellaarinen tekonivelkomponentti voi mennä sijoiltaan sopimattoman fyysisen aktiviteetin tai trauman vuoksi tai muista biomekaanisista tekijöistä johtuen.
- Polven kokotekonivelen komponenttien löystymistä voi ilmetä. Varhainen löystyminen voi johtua siitä, että kiinnittyminen luuhun ei alun perinkään ollut riittävä, latentista infektiosta, tekonivelen liian varhaisesta kuormittamisesta, väärästä kohdistuksesta tai traumasta. Myöhäisvaiheessa löystymisen syynä voi olla trauma, infektio, biologiset komplikaatiot, osteolyysi tai mekaaniset ongelmat, jolloin seurauksena voi olla luun eroosio ja/tai kipu.
- Polven kokotekonivelen tibiaalisten, femoraalisten ja patellaarikomponenttien väsymismurtumia on ilmennyt pienessä osassa tapauksia. Polvitekonivelen komponenttien murtumat voivat johtua komponentin alla olevan luun riittämättömästä tuesta tai komponenttien riittämättömästä kiinnityksestä.
- Perifeerisiä neuropatioita, hermovauriota, verenkiertohäiriöitä ja heterotooppisen luun muodostusta saattaa esiintyä.
- Kaikkiin kokotekonivelleikkauksiin saattaa liittyä vakavia komplikaatioita. Näitä komplikaatiota voivat olla mm.: virtsa- ja sukuelinten, ruuansulatuskanavan ja verenkiertoelinten häiriöt kuten veritulpat, bronkopulmonaariset häiriöt, (mm. emboliat), sydäninfarkti tai kuolema.
- Polyeteenikomponenttien kulumista on ilmennyt ja lääketieteellisessä kirjallisuudessa siihen on raportoitu liittyneen luun resorptiota, tekonivelen löystymistä ja infektioita.
- Tekonivelten istutuksen jälkeen on raportoitu esiintyneen metallille herkistymisestä aiheutuneita reaktioita.
- Haittavaikutukset voivat johtaa uusintaleikkauksiin, revisioihin, kyseisen nivelen luudutukseen ja/tai raajan amputointiin.
- Pehmytkudosten epätasapaino voi aiheuttaa liiallista kulumista ja/tai istutteen rikkoutumisen.
- Kuten kaikkien istutteiden ollessa kyseessä, tekonivelen komponenttien ympärillä voi ilmetä oireetonta, paikallista progressiivista luun resorptiota (osteolyysiä), joka aiheutuu vierasesinereaktiosta sementti-, metalli-, suurimolekyylipainopolyeteeni(UHMWPE)- ja/tai keraamihiukkasille. Hiukkasmuodostus aiheutuu komponenttien välisestä sekä komponenttien ja luun välisestä vuorovaikutuksesta, ensisijaisesti adheesion, hankauksen ja rakenteiden väsymismuutosten aiheuttamasta kulumisesta. Hiukkasia voi lisäksi muodostua jonkin kolmannen tekijän kulumisesta. Osteolyysi voi myöhemmin aiheuttaa komplikaatioita, mm. tekonivelen ja sen osien löystymistä, minkä vuoksi tekonivelen komponenttien poistaminen ja korvaaminen saattaa tulla aiheelliseksi.
- Tiedetään, että metalli- ja polyeteenikomponenteista voi ajan mittaan irrota hyvin pieniä hiukkasia normaalin käytön aikana . Vaikka suurin osa tätä hiukkasjätettä jääkin asianomaiseen niveleen (esim. nivelkalvoon) tai joutuu ympäröivään arpikudokseen, mikroskooppiset hiukkaset voivat mahdollisesti kulkeutua tai siirtyä nivelen ulkopuolelle elimistön eri osiin. Tällä hetkellä tieto näistä komponenteista peräisin olevien jätehiukkasten ja mikroskooppisten hiukkasten kohtalosta on puutteellista. On osoitettu, että mikroskooppiset jätehiukkaset voivat kulkeutua elimistöön ja niiden joskus kuvattu kertyneen imusolmukkeisiin ja elimistön muihin osiin. Vaikka tähän saakka ei ole raportoitu esiintyneen näiden hiukkasten aiheuttamia merkittäviä terveyshaittoja, niiden kulkeutuminen ja/tai kertyminen elimistöön on kuvattu lääketieteellisessä kirjallisuudessa. Ottaen huomioon, että potilaita, joilla on tällaisia tekoniveliä, on voitu seurata vain suhteellisen lyhyen aikaa, sekä sen tosiasian, että näitä tekoniveliä nykyisin istutetaan nuoremmille potilaille, minkä vuoksi tekonivelet ovat potilaan elimistössä yhä pitempiä aikoja, on sanottava, että näiden hiukkasten pitkäaikaisvaikutuksia, jos niitä on, ei tunneta. Teoreettisesti voisivat seuraavat pitkäaikaisvaikutukset tulla kysymykseen:
  - **Syöpä:** Tällä hetkellä ei ole olemassa tieteellistä näyttöä siitä, että metalli- tai polyeteenijätteillä olisi yhteyttä syöpään. Tätä mahdollisuutta ei kuitenkaan voida sulkea pois.

– **Lymfadenopatia ja kertyminen muihin kudoksiin ja elimiin:** Muutamissa raporteissa on kuvattu kulumajätehiukkasten kertyneen läheisiin ja kauempana sijaitseviin imusolmukkeisiin. Vaikka näiden kertymien ei ole raportoitu aiheuttaneen terveydelle haittaa tai sairauksia, niiden olemassaolo on hyvä tuntea diagnoosiin pääsyn helpottamiseksi ja niiden erottamiseksi muista epäilyttävistä muutoksista (esim. syöpä).
– **Systeemisairaudet:** On esiintynyt jonkin verran pohdiskelua siitä, olisiko kulumajätteen kulkeutumisella ja toistaiseksi tunnistamattomilla systeemivaikutuksilla mitään yhteyttä. On mahdollista, että joitakin pitkäaikaisvaikutuksia voidaan osoittaa joskus tulevaisuudessa, mutta koska on olemassa hyvin vähän tieteellistä näyttöä kulkeutuneen kulumajätteen ja systeemisairauksien välisestä yhteydestä, uskotaan tällä hetkellä, että näistä tekonivelistä koituva hyöty on selvästi suurempi kuin minkään mahdollisen teoreettisen pitkäaikaisvaikutuksen aiheuttama riski.

Yhteisvaikutukset magneettikuvauksen kanssa

Triathlon-polviniveljärjestelmien turvallisuutta ja yhteensopivuutta magneettikuvausympäristössä ei ole selvitetty. Triathlon-polviniveljärjestelmän mahdollista kuumentumista tai kulkeutumista magneettikuvausympäristössä ei ole selvitetty.

Sterilointi

- Tämä polven kokotekonivelen komponentti on steriloitu gammasäteilyllä tai vetyperoksidikaasuplasmalla. Sterilointimenetelmä on merkitty pakkaukseen.
- Kaikkien steriilien tuotteiden pakkaukset on ennen avaamista tarkastettava steriiliaidakkeen vaurioiden varalta. Jos tällaisia vaurioita havaitaan, tuotetta on pidettävä epästeriilinä. Erityisiä sovitustekonivelkomponentteja on saatavana, jotta steriiliä pakkausta ei tarvitsisi avata ennen komponentin käyttöä.
- On varottava, ettei komponentti kontaminoidu. Jos tämä tuote kontaminoituu, se on hävitettävä.
- Jos pakkaus avataan, mutta tuote jää käyttämättä, komponenttia ei saa steriloida uudelleen, vaan se on hävitettävä tai palautettava tavarantoimittajalle.
- Tuotetta ei saa käyttää pakkausmerkinnöissä mainitun viimeisen käyttöpäivämäärän jälkeen, sillä pakkauksen kelpoisuutta tämän päivämäärän jälkeen ei ole validoitu.
- Kertakäyttöisiä komponentteja ei saa poistamisen jälkeen istuttaa uudestaan, sillä näiden toimenpiteiden aiheuttamat voimat voivat rikkoa komponentin, vaikuttaa sen kokoon ja/tai sen pinnoitteeseen. Uudelleenkäytettyjen tuotteiden steriiliyttä ei voida taata, sillä niiden puhdistuksen ja uudelleensteriloinnin tehokkuutta ei ole varmistettu.

VAROITUS: **YHDYSVALTAIN LAIN MUKAAN TÄTÄ TUOTETTA SAA MYYDÄ VAIN LÄÄKÄRI TAI LÄÄKÄRIN MÄÄRÄYKSESTÄ.**

VAROITUS: Komponenttien, joissa on merkintä "Cemented Use Only" (vain sementillä kiinnitettäväksi tarkoitettu) kiinnittämiseen saa käyttää vain sementtiä.

CE-merkin tila ja laillinen valmistaja esitetään pakkausmerkinnöissä. CE-merkki on kelpoinen vain, jos se sisältyy pakkausmerkintöihin.

Seuraavassa taulukossa on luettelo lyhennyksistä, joita Howmedica Osteonics Corp. käyttää pakkausmerkinnöissä:

Nimi	Lyhenne	Nimi	Lyhenne
Alfakoodi	ALPH CDE	Kaula	NK
Kulma	ANG	Offset	OFFST
Aste tai °	DEG or °	Ulkoläpimitta	OD
Läpimitta	DIA	Oikea	RT ▶
Erittäin syvä	XDP	Ruuvinreiät	SCR HLS
Erittäin suuri	XLGE	Sivu	SDE
Erittäin pieni	XSM	Koko	SZE
Nuppi	HD	Pieni	SM
Korkeus	HT	Vakio	STD
Sisäläpimitta	ID	Kartio	TPR
Sisäke	INSR	Paksuus	THKNS
Suuri	LGE	Tyyppi	TYP
Vasen	◀ LFT	Kera	W/
Pituus	LNTH	Ilman	W/O
Keskikoko	MED		

Dansk

HOWMEDICA OSTEONICS TRIATHLON TRITANIUM TIL TOTAL KNÆALLOPLASTIK

Beskrivelse

Howmedica Osteonics Corp.'s totale knæsystemer omfatter en grundskinne til Triathlon Tritanium, som er fremstillet til anvendelse med Triathlon Primary knæsystems femurkomponenter, tibiaindsatser og patellakomponenter til total rekonstruktiv udskiftning af knæleddet. Specifikke karakteristika for hver enkelt anordning står opført på produktets etiket. Triathlon Tritanium-grundskinne er indiceret til både cementfri og cementeret anvendelse

Femurkomponenter: Triathlon Tritanium-grundskinne er kompatibel med Triathlon korsbåndsbevarende (CR) og korsbåndopgivende (posteriort stabiliseret – PS) designs.

Tibiakomponenter: Triathlon Tritanium-grundskinne er kompatibel med Triathlon tibiaindsatser i korsbåndsbevarende (CR), posteriort stabiliserede (PS) og kondylærstabiliserende (CS) designs. Tibiaindsatser leveres i en række tykkelser og tvangsgrader.

Bemærk: Triathlon Tritanium-grundskinne er emballeret sammen med en køllepolstring. Køllepolstringen skal kun anvendes ved fastsættelsen af tibiagrundskinnen, og skal bortskaffes, når fastsættelsen er afsluttet. Køllepolstringen må ikke implanteres.

Patellakomponenter: Overfladebehandlende patellakomponenter fås i udformninger med symmetrisk og asymmetrisk ren plastik og bagbeklædning af metal. Anvendelsen af en patellakomponent er valgfri. Triathlon Tritanium-grundskinne er kompatibel med alle Triathlon patellakomponenter.

Materialer

• ASTM F-75 koboltkromlegering	Femurkomponenter
• ASTM F-90 koboltkromlegering	Låsetråd til tibiaindsatser
• ASTM F-1537 koboltkromlegering	Femurstifter
• ASTM F-136 titanlegering	Tibiakomponenter
• ASTM F-67 CP titan	Tibiakomponenter
• ASTM F-1185 calciumfosfat	Femurkomponenter, patellakomponenter
• ASTM F-648 polyethylen med ultrahøj molekylvægt	Tibialejeindsats, patellakomponenter

Indikationer

Generelle indikationer for total knæartroplasti:

- Smertefulde, invaliderende ledsygdomme i knæet, der stammer fra: noninflammatoriske degenerative ledlidelser (herunder osteoartritis, traumatisk artritis eller avaskulær nekrose), reumatoid artritis eller posttraumatisk artritis.
- Posttraumatisk tab af knæledskonfiguration og funktion.
- Moderat varus-, valgus- eller fleksionsdeformitet, hvor ledbåndsstrukturerne kan vende tilbage til tilstrækkelig funktion og stabilitet.
- Revision af tidligere mislykkede knæudskiftninger eller et andet indgreb.
- Fraktur af den distale femur og/eller proksimale tibia, der ikke kan stabiliseres med standard frakturbehandlingsmetoder.

Triathlon Tritanium-grundskinne er indiceret til både cementfri og cementeret anvendelse.

Yderligere indikationer for posteriort stabiliseret (PS) komponenter:

- Mangel på ledbåndsstabilitet som kræver implantatlejeoverfladegeometri med øget tvang.
- Posteriort korsbånd, der enten mangler eller ikke fungerer.
- Alvorlig anteroposterior mangel på stabilitet i knæleddet.

Kontraindikationer

- Alle aktive eller suspekte latente infektioner i eller omkring knæleddet.
- Fjerntliggende infektionssteder, som kan forårsage hæmatogen smitte af implantationsstedet.
- Enhver mental eller neuromuskulær lidelse, der kan skabe en uacceptabel risiko for manglende protesestabilitet, protesefikseringssvigt eller komplikationer under postoperativ pleje.
- Knoglemateriale, der er svækket af sygdom, infektion eller tidligere implantation, der ikke kan yde tilstrækkelig støtte og/eller fiksering for protesen.
- Umodent skelet.
- Alvorlig mangel på stabilitet i knæleddet som følge af manglende helhed og funktion af sideordnede ledbånd.
- Obesitas. En obes eller overvægtig patient kan udsætte protesen for belastninger, som kan føre til, at anordningens fiksering svigter, eller at selve anordningen svigter.

Forholdsregler

- Kirurger skal råde patienterne både om begrænsningerne ved rekonstruktionen og nødvendigheden af at beskytte implantatet mod fuld vægtbelastning, indtil der forekommer tilstrækkelig fiksering og heling. For kraftig aktivitet og traume på ledalloplastikken er sandsynligvis årsagen til, at rekonstruktionen mislykkes på grund af løsrivelse, fraktur og/eller slitage på proteseimplantaterne. Løsrivelse af komponenterne kan resultere i forhøjet produktion af slidpartikler, såvel som beskadigelse af knoglen, hvilket gør det sværere at foretage et vellykket revisionsindgreb.
- Kirurger bør advare patienten om at begrænse aktiviteter og beskytte det udskiftede led mod urimelige belastninger, og om at følge lægens anvisninger mht. follow-up og behandling.
- Kirurger skal advare patienter om potentielle bivirkninger, herunder anordningens begrænsede levetid samt behovet for postoperativ beskyttelse af implantatet. Kirurgen bør advare patienterne om, at protesen ikke vil gengive fleksibiliteten, styrken, pålideligheden eller holdbarheden af et normalt, sundt led, og at implantatet kan gå i stykker eller blive beskadiget, hvis det udsættes for anstrengende aktivitet eller traume.
- Passende valg, anbringelse og fiksering af knæalloplastikkomponenterne er kritisk vigtige faktorer, som har indflydelse på implantatets holdbarhed. Som det er tilfældet med alle andre proteseimplantater, påvirkes disse komponenters holdbarhed af adskillige biologiske, biomekaniske og andre eksterne faktorer, der begrænser deres holdbarhed. Som følge heraf er det yderst vigtigt at følge de indikationer, kontraindikationer, forholdsregler og advarsler, der gælder for produktet for potentielt at maksimere holdbarheden.

Anvendelse og implantation

- De anbefalede prøvekomponenter bør anvendes til at afgøre størrelse, prøvereduktion og til evaluering af bevægelsesområdet. Derved bevares de aktuelle implantaters helhed og deres sterile indpakning.
- Der findes radiografiske skabeloner til at assistere med den præ-operative afgørelse af komponentstørrelse og stil.
- Udvis omhu ved fjernelse af knoglesplinter, knoglecementfragmenter og metallisk debris fra implantationsstedet for at reducere risikoen for debrisinduceret accelereret slitage af implantatets ledoverflader.
- Howmedica Osteonics Corp.'s kirurgiske protokoller giver yderligere oplysninger om fremgangsmåde.
- Se etiketten på produktet for oplysninger om specifik kompatibilitet. I reglen gælder følgende:
  - Brug kun PS-femurprodukter med PS-tibialejer
  - CR-femurprodukter må kun anvendes med CR-tibialejer
  - Brug enten PS- eller CR-femurprodukter med CS-tibialejer

Information til patienter

- Kirurgen skal underrette patienten både om rekonstruktionens begrænsninger og om nødvendigheden af at beskytte implantatet mod overbelastning forårsaget af fuld vægtbelastning, inden der er tilstrækkelig fiksering og heling. For kraftig aktivitet og traume på ledalloplastikken er sandsynligvis årsagen til, at rekonstruktionen mislykkes på grund af løsrivelse, fraktur og/eller slitage på proteseimplantaterne. Løsrivelse af komponenterne kan resultere i forhøjet produktion af slidpartikler, såvel som beskadigelse af knoglen, hvilket gør det sværere at foretage et vellykket revisionsindgreb.
- Kirurgen skal advare patienten om at begrænse aktiviteter og beskytte det udskiftede led mod urimelige belastninger, og om at følge lægens anvisninger mht. follow-up og behandling.
- Kirurgen bør advare patienten om de kirurgiske risici, og gøre opmærksom på mulige bivirkninger. Kirurgen bør advare patienten om, at protesen ikke vil genoprette et normalt, sundt led, og at implantatet kan gå i stykker eller blive beskadiget, hvis det udsættes for anstrengende aktivitet eller traume, samt at anordningen har en begrænset holdbarhed, og at det muligvis bliver nødvendigt at udskifte den en gang i fremtiden.
- Der kan opstå forbigående bakteriæmi i det daglige liv. Et besøg hos tandlægen, endoskopiske undersøgelser og andre mindre kirurgiske indgreb er også blevet forbundet med forbigående bakteriæmi. Det kan eventuelt være tilrådeligt at behandle med forebyggende antibiotika før og efter disse indgreb for at undgå infektion på implantatstedet.

Advarsler

- Alle beskadigede eller forkert håndterede implantater skal bortskaffes.
- Et implantat må aldrig genbruges, selvom det ser ubeskadiget ud.
- Køllepolstringen må ikke implanteres. Køllepolstringen må kun anvendes ved fastsættelsen af tibiagrundskinnen. Den skal fjernes og bortskaffes umiddelbart efter fastsættelsesprocessen.
- Polerede kontaktflader i lejet må ikke komme i kontakt med hårde eller slibende flader.
- Lejeoverflader skal altid være rene og fri for debris inden montering.
- Hvis et implantat kontureres eller bøjes, er der risiko for at reducere dets slidstyrke og for at medføre svigt ved belastning.
- Indsatsens retentionstråd af metal må ikke håndteres eller fjernes, da den er yderst vigtig for samlingens sikkerhed. Bortskaf alle tibialejeindsatser, hvor retentionsmetaltråden ser ud, som om den er beskadiget eller forkert behandlet. Hvis der foretages ændringer i samlingen, risikeres det, at retentionsmekanismen kommer til at fungere forkert.
- Der bør udvises omhu for at undgå at skære gennem de kirurgiske handsker ved håndtering af alle ortopædiske anordninger med skarpe kanter.
- Undtagen hvor noteret, fraråder Howmedica Osteonics Corp. på det kraftigste, at der anvendes knæalloplastikkomponenter af et andet fabrikat i forbindelse med alle knæalloplastikkomponenter fra Howmedica Osteonics. Denne type anvendelse vil ophæve Howmedica Osteonics Corp.'s ansvar for den performance, der ydes af det deraf opståede blandede komponentimplantat.
- Howmedica Osteonics Corp. fraråder på det kraftigste, at der anvendes knogleskruer af et andet fabrikat i forbindelse med alle knækomponenter fra Howmedica Osteonics på grund af variationer mellem skruehoved- og skruesædekonfigurationer.
- En knæalloplastikkomponent kan fjernes med overlæg gennem forsigtig anvendelse af skærebor, tynde og smalle osteotomer og forsigtig udtrækningskraft.
- Når en tibiaindsats af plastic fjernes med overlæg, efter den er samlet i metalgrundskinnen, ødelægges plasticindsatsen. Udvis omhu, så tibiagrundskinnens overflade ikke bliver udsat for skrammer eller hak, mens indsatsen fjernes.
- Send alle pakker med fejl i den sterile barriere retur til leverandøren. **Må ikke resteriliseres.**

Bivirkninger

- Selvom den forventede holdbarhed af komponenterne i en knæledsalloplastik er vanskelig at vurdere, er den dog begrænset. Disse komponenter er lavet af fremmedmateriale, der anbringes inden i kroppen for om muligt at genoprette mobiliteten eller nedsætte smerterne. Dog kan komponenterne-- der pga. de mange biologiske, mekaniske og fysiokemiske faktorer, der har indflydelse på disse anordninger, men som ikke kan vurderes *in vivo*-- ikke forventes for evigt at holde til de samme aktivitetsniveauer og belastninger som normal knogle. Kirurger bør rådgive patienter mod at have urealistiske forventninger om protesens levetid.
- Der kan forekomme dislokation i femur-, tibia- eller patellaprotesen forårsaget af patientens uhensigtsmæssige aktivitet, traume eller andre biomekaniske faktorer.
- Der kan forekomme løsrivelse af komponenter i knæalloplastikken. Tidlig mekanisk løsning kan forårsages af utilstrækkelig oprindelig fiksering, latent infektion, for tidlig belastning af protesen, forkert komponenttilpasning eller traume. Sen løsning kan forårsages af traume, infektion, biologiske komplikationer, bl.a. osteolyse, eller mekaniske problemer med efterfølgende mulighed for knogleerosion og/eller smerter.
- I en lille procentdel tilfælde er der forekommet slidfrakturer i knæalloplastikkomponenter, inklusive tibia-, femur- og patellakomponenter. Fraktur af en knækomponent kan indtræffe på grund af utilstrækkelig komponentstøtte fra den underliggende knogle eller dårlig komponentfiksering.
- Der kan forekomme perifere neuropatier, nerveskader, svækket kredsløb og heterotopisk knogledannelse.
- Der kan opstå alvorlige komplikationer i forbindelse med enhver total ledalloplastikoperation. Disse komplikationer omfatter, men er ikke begrænsede til: urogenitale lidelser, gastrointestinale lidelser, vaskulære lidelser, herunder tromber, bronkopulmonære lidelser, herunder emboli, myokardieinfarkt eller død.
- Der er forekommet tilfælde af slid på komponenter af polyethylen, og rapporter i litteraturen sætter denne forekomst i forbindelse med knogleresorption, løsning og infektion.
- Der er blevet rapporteret overfølsomhed over for metal efter ledalloplastik.
- Bivirkninger kan nødvendiggøre en ny operation, revision, artrodese af det led, der er involveret og/eller amputation af ekstremiteten.
- Ubalance i det bløde væv og/eller slaphed er blevet relateret til forkert komponenttilpasning, som kan føre til tidlig slitage og/eller svigt af implantatet.
- I lighed med alle implantationsanordninger kan der forekomme asymptomatisk, lokaliseret, progressiv knogleresorption (osteolyse) omkring protesekomponenterne som følge af fremmedlegemereaktion på partikler af cement, metal, polyethylen med ultrahøj molekylvægt (UHMWPE) og/eller keramik. Der dannes partikler ved gensidig påvirkning mellem komponenterne så vel som mellem komponenter og knogler, først og fremmest gennem mekanismer som f.eks. adhærence, abrasion og slid. Sekundært kan der også produceres partikler gennem tredjepartsslid. Osteolyse kan føre til fremtidige komplikationer, bl.a. løsrivelse, hvor det bliver nødvendigt at fjerne og udskifte protesekomponenter.
- Det vides, at meget små partikler fra metal- eller polyethylenkomponenter ved normal brug og med tiden kan skalle af komponenten. Selvom det meste af dette debris bliver i de pågældende led (f.eks. indeholdt i ledvæsken) eller er indfanget i omgivende arvæv, kan mikroskopiske partikler muligvis migrere ud af leddet til andre dele af kroppen. Der er aktuelt ubesvarede spørgsmål om debris og mikroskopiske partikler, der kan blive dannet fra disse komponenter. Det er blevet vist, at mikroskopiske debrispartikler kan blive disseminerede (migrere) gennem kroppen, og de er i visse tilfælde blevet beskrevet som akkumulerende i lymfeknuder og andre dele af kroppen. Selv om der ikke er blevet indberettet nogen betydningsfulde helbredsmæssige komplikationer resulterende fra disse partikler, er deres bevægelse og/eller opsamling i kroppen blevet beskrevet i litteraturen. I betragtning af det utilstrækkelige tidsrum i hvilket patienter med disse anordninger er blevet observeret, og den kendsgerning, at disse anordninger nu bliver anvendt i yngre patienter og forbliver i kroppen i stadig længere tidsperioder, kan det konstateres, at eventuelle langtidseffekter fra disse partikler er ukendte. De teoretiserede langtidseffekter indbefatter:
  - **Kræft:** Der findes i øjeblikket ingen videnskabelige beviser, som forbinder metal- eller polyethylendebris med kræft. En sådan mulighed kan dog ikke udelukkes.
  - **Lymfeadenopati og akkumulering i andre væv/organer:** Der har været nogle få indberetninger angående akkumulering af sliddebris i lymfeknuder (proksimale og distale). Selv om der ikke

er blevet indberettet nogen helbredsmæssige komplikationer eller sygdomsforløb stammende fra disse akkumuleringer, bør deres tilstedeværelse erkendes for at lette diagnosen og undgå forvirring mht. eventuelle læsioner, hvad enten de er maligne eller benigne.

– **Systemisk sygdom:** Der har været spekulation omkring, at der kunne være en forbindelse mellem migration af debris og visse hidtil uspecificerede systemiske virkninger. Tidseffekter kan muligvis demonstreres i fremtiden, men da der er meget få videnskabelige data, der tyder på en forbindelse mellem migration af debris og systemisk sygdom, menes fordelene ved disse anordninger klart at overstige de potentielle risici for sådanne teoretiske langtidsvirkninger.

Interaktion med MR-scanning

Triathlon knæsystemet er ikke evalueret i forhold til sikkerhed i og kompatibilitet med et MR-miljø. Triathlon knæsystemet er ikke afprøvet i forhold til opvarmning eller migration i et MR-miljø.

Sterilisering

- Denne totale knækomponent er blevet steriliseres med gammabestråling eller brintoverilte gasplasma. Se pakkens etiket for steriliseringsmetoden.
- Indpakningen af alle sterile produkter skal efterses for fejl i den sterile barriere inden åbning. Ved tilstedeværelse af en sådan fejl skal produktet antages at være usterilt. Der findes særlige prøveproteser, så det ikke er nødvendigt at åbne nogen del af den sterile pakke, inden komponenten skal bruges.
- Der skal udvises omhu for at undgå kontaminering af komponenten. I tilfælde af kontaminering skal produktet bortskaffes.
- Hvis pakken er åbnet, men produktet ikke har været brugt, må komponenten ikke resteriliseres, og den skal bortskaffes eller returneres til leverandøren.
- Anordningen må ikke anvendes efter den udløbsdato, der er vist på etiketten, da emballagen ikke er blevet valideret ud over denne dato.
- Engangsproteser kan ikke eksplanteres og derefter genimplanteres, da de fysiske kræfter, der udøves ved disse foranstaltninger, kan kompromittere den fysiske integritet og/eller overfladebelægningen på proteserne. Desuden kan sterilitet ikke garanteres for genbrugte anordninger, da rensnings- og resteriliseringsprocedurer ikke er blevet verificerede.

OBS! **IFØLGE AMERIKANSK LOVGIVNING MÅ DENNE ANORDNING KUN ANVENDES AF ELLER PÅ BESTILLING AF EN LÆGE.**

ADVARSEL: Komponenter, der er mærket “Cemented Use Only” (Kun til cementeret anvendelse) må kun implanteres med knoglecement.

Se produktmærkaten for CE-mærkestatus og lovmæssig fabrikant. CE-mærket er kun gyldigt, hvis det også findes på produktetiketten.

Den følgende tabel indeholder en liste over forkortelser, som anvendes på Howmedica Osteonics Corp. produktmærkning:

Glose	Forkortelse	Glose	Forkortelse
Alfakode	ALPH CDE	Hals	NK
Vinkel	ANG	Forskydning	OFFST
Grader	DEG or °	Udvendig diameter	OD
Diameter	DIA	Højre	RT ▶
Ekstra dyb	XDP	Skruehuller	SCR HLS
Ekstra stor	XLGE	Side	SDE
Ekstra lille	XSM	Størrelse	SZE
Hoved	HD	Lille	SM
Højde	HT	Standard	STD
Indvendig diameter	ID	Konusform	TPR
Indsats	INSR	Tykkelse	THKNS
Stor	LGE	Type	TYP
Venstre	◀ LFT	Med	W/
Længde	LNTH	Uden	W/O
Medium	MED		

Nederlands

GEBRUIKSAANWIJZING VOOR HOWMEDICA OSTEONICS' TRIATHLON TRITANIUM TOTALE KNIE

Beschrijving

De totale kniesystemen van Howmedica Osteonics omvatten de Triathlon Tritanium basisplaat die ontwikkeld is voor toepassing in combinatie met femur- en patellacomponenten en tibia-inlegdelen van het Triathlon primaire kniesysteem voor totale reconstructieve vervanging van het kniegewricht. De specifieke eigenschappen van elk protheseonderdeel staan beschreven op het productetiket. De Triathlon Tritanium basisplaat is geïndiceerd voor zowel ongecementeerde als gecementeerde toepassing.

Femurcomponenten: De Triathlon Tritanium basisplaat is compatibel met de Triathlon kruisbandsparende (CR) en kruisbandopofferende (posterieur gestabiliseerde - PS) uitvoeringen.

Tibiacomponenten: De Triathlon Tritanium basisplaat is compatibel met Triathlon tibia-dragerinlegdelen in kruisbandsparende (CR), posterieur gestabiliseerde (PS) en condylair gestabiliseerde (CS) uitvoeringen. Tibia-inlegdelen zijn verkrijgbaar in een reeks verschillende dikten en met verschillende maten van bewegingsbeperking.

Opmerking: De Triathlon Tritanium basisplaat is verpakt samen met een impactorkussen. Het impactorkussen wordt alleen gebruikt bij de stap waarbij de tibiabasisplaat wordt vastgeslagen en moet worden weggegooid zodra de component vastzit. Het impactorkussen is niet bestemd voor implantatie.

Patellacomponenten: Patella-resurfacingcomponenten zijn verkrijgbaar in symmetrische en asymmetrische uitvoeringen, zowel geheel van kunststof als aan de achterkant met metaal bekleed. Gebruik van een patellacomponent is optioneel. De Triathlon Tritanium basisplaat is compatibel met alle Triathlon patellacomponenten.

Materialen

• ASTM F-75 chroomkobaltlegering	Femurcomponenten
• ASTM F-90 chroomkobaltlegering	Borgdraad voor tibia-dragerinlegdelen
• ASTM F-1537 chroomkobaltlegering	Femurpinnen
• ASTM F-136 titaanlegering	Tibiacomponenten
• ASTM F-67 CP titaan	Tibiacomponenten
• ASTM F-1185 calciumfosfaat	Femurcomponenten, patellacomponenten
• ASTM F-648 Ultra high molecular weight polyethylene	Tibiadragerinlegdelen, patellacomponenten

Indicaties

Algemene indicaties voor een totale knieartroplastiek (TKR):

- Pijnlijke, invaliderende aantasting van het kniegewricht ten gevolge van: niet-inflammatoire degeneratieve aantasting van het gewricht (waaronder osteoartritis, traumatische artritis en avasculaire kopnecrose) reumatoïde artritis of posttraumatische artritis.
- Posttraumatisch verlies van vorm en functie van het kniegewricht.
- Matige varus-, valgus- of flexieafwijking, waarbij weer een adequate functie en stabiliteit van het bandapparaat verkregen kan worden.
- Revisie van een eerdere niet-geslaagde knievervanging of andere procedure.
- Fractuur van het distale femur en/of de proximale tibia die met de gebruikelijke factuurbehandelingsmethoden niet gestabiliseerd kan worden.

De Triathlon Tritanium basisplaat is geïndiceerd voor zowel ongecementeerde als gecementeerde toepassing.

Additionele indicaties voor posterieur gestabiliseerde (PS) componenten:

- Instabiliteit van het bandapparaat, waardoor de vorm van het loopvlak van het implantaat meer bewegingsbeperking moet hebben.
- Afwezige of niet-functionele achterste kruisband.
- Ernstige anteroposterieure instabiliteit van het kniegewricht.

Contra-indicaties

- Elke actieve of vermoede latente infectie in of rond het kniegewricht.
- Infectiehaarden op afstand (waardoor de infectie zich hematogeen naar de implantatieplaats kan uitbreiden).
- Elke mentale of neuromusculaire aandoening die een onaanvaardbaar risico van instabiliteit van de prothese, falen van de prothesefixatie of complicaties in de postoperatieve zorg met zich meebrengt.
- Door ziekte, infectie of een eerdere implantatie aangetaste botmassa die onvoldoende steun en/of fixatiemogelijkheden biedt voor de prothese.
- Onvolgroeidheid van het skelet.
- Ernstige instabiliteit van het kniegewricht, ten gevolge van een aangetast, niet-functioneel collateraal ligament.
- Zwaarlijvigheid. Een patiënt met overgewicht of vetzucht (obesitas) kan de prothese dusdanig belasten dat de fixatie van het implantaat of het implantaat zelf kan falen.

Voorzorgsmaatregelen

- De chirurg dient de patiënt in te lichten over zowel de beperkingen van de constructie als de noodzaak het implantaat te beschermen tegen volledige belasting, totdat voldoende fixatie en genezing plaats hebben gevonden. Overmatige activiteit en trauma aan het vervangen gewricht zijn verantwoordelijk geacht voor reconstructies die gefaald hebben door losraken, breken en/of slijtage van de prothetische implantaten. Losraken van de componenten kan verhoogde productie van slijtagedeeltjes ten gevolge hebben, evenals beschadiging van het bot, waardoor een succesvolle revisie-ingreep moeilijker wordt.
- De chirurg dient de patiënt te waarschuwen zijn/haar activiteiten te beperken en het vervangen gewricht te beschermen tegen een onredelijke mate van stress, en de instructies van de arts met betrekking tot follow-up en nabehandeling in acht te nemen.
- De chirurg dient de patiënt te waarschuwen voor mogelijke ongewenste effecten waaronder de eindige levensduur van de prothese en de noodzaak van postoperatieve bescherming van het implantaat. De chirurg moet de patiënt waarschuwen dat het implantaat een normaal gezond gewricht qua flexibiliteit, sterkte, betrouwbaarheid en duurzaamheid niet kan evenaren, dat het implantaat kan breken of beschadigd kan raken ten gevolge van intensieve inspanning of trauma.
- De juiste keuze, plaatsing en fixatie van totale kniecomponenten zijn essentiële factoren die de bruikbare levensduur van het implantaat beïnvloeden. Zoals bij alle prothetische implantaten, wordt de duurzaamheid van deze componenten beïnvloed door talloze biologische, biomechanische en andere extrinsieke factoren die de bruikbare levensduur beperken. Het is daarom essentieel strikt de hand te houden aan de voor dit product geldende indicaties, contra-indicaties, voorzorgsmaatregelen en waarschuwingen om het zo lang mogelijk te kunnen blijven gebruiken.

Gebruik en implantatie

- Gebruik de aanbevolen pasprothesen teneinde, bij het bepalen van de maat, de proefreductie en de evaluatie van de bewegingsuitslag, de integriteit van de eigenlijke implantaten en hun steriele verpakking te waarborgen.
- Als hulpmiddel bij de preoperatieve voorspelling van componentafmeting en -type zijn radiografische sjablonen verkrijgbaar.
- Verwijder zorgvuldig alle botsplinters, botcementdeeltjes en metaaldébris uit het implantatiegebied om het risico van versnelde slijtage van de gewrichtsoppervlakken van het implantaat ten gevolge van deeltjes te verkleinen.

- De chirurgische protocollen van Howmedica Osteonics Corp. bevatten aanvullende informatie betreffende de procedures.
- Raadpleeg het productetiket voor specifieke productcompatibiliteit. In het algemeen geldt het volgende:
  - Gebruik PS femurcomponenten alleen met PS tibiadragers
  - Gebruik CR femurcomponenten alleen met CR tibiadragers
  - Gebruik ofwel PS ofwel CR femurcomponenten met CS tibiadragers

Informatie voor patiënten

- De chirurg dient de patiënt in te lichten over zowel de beperkingen van de constructie als de noodzaak het implantaat te beschermen tegen volledige belasting, totdat voldoende fixatie en genezing plaats hebben gevonden. Overmatige activiteit en trauma aan het vervangen gewricht zijn verantwoordelijk geacht voor reconstructies die gefaald hebben door losraken, breken en/of slijtage van de prothetische implantaten. Losraken van de componenten kan verhoogde productie van slijtagedeeltjes ten gevolge hebben, evenals beschadiging van het bot, waardoor een succesvolle revisie-ingreep moeilijker wordt.
- De chirurg dient de patiënt te waarschuwen zijn/haar activiteiten te beperken en het vervangen gewricht te beschermen tegen een onredelijke mate van stress, en de instructies van de arts met betrekking tot follow-up en nabehandeling in acht te nemen.
- De chirurg dient de patiënt te waarschuwen voor de risico's van chirurgisch ingrijpen en mogelijke nadelige effecten. De chirurg dient de patiënt te waarschuwen dat het implantaat geen normaal gezond gewricht evenaart, dat het implantaat kan breken of beschadigd kan raken ten gevolge van intensieve inspanning of trauma en dat het implantaat een eindige gebruiksduur heeft en mogelijk in de toekomst vervangen moet worden.
- Voorbijgaande bacteriëmie kan in het dagelijks leven voorkomen. Tandheelkundig werk, endoscopisch onderzoek en andere kleine chirurgische ingrepen zijn ook in verband gebracht met voorbijgaande bacteriëmie. Antimicrobiële profylaxe voor en na dergelijke procedures verdient aanbeveling om infectie ter plaatse van het implantaat te voorkomen.

Waarschuwingen

- Gooi alle beschadigde of verkeerd behandelde implantaten weg.
- Gebruik een implantaat nooit opnieuw, ook al ziet het er onbeschadigd uit.
- Implanteer het impactorkussen niet. Het impactorkussen wordt alleen gebruikt bij de stap waarbij de tibiacomponent wordt vastgeslagen. Verwijder het en gooi het onmiddellijk na het vastslaan weg.
- Gepolijste loopvlakken mogen niet in contact komen met harde of schurende oppervlakken.
- Draagvlakken moeten vóór assemblage altijd schoon zijn en geen débris bevatten.
- Verbuiging of vervorming van een implantaat kan de sterkte doen afnemen als gevolg van materiaalmoeheid en bij belasting tot falen leiden.
- De metalen retentiedraad op het inlegdeel mag niet aangeraakt of verwijderd worden, aangezien deze cruciaal is voor de betrouwbaarheid van het samenstel. Gooi een tibia-dragerinlegdeel weg als de metalen retentiedraad er beschadigd of verkeerd behandeld uitziet. Pogingen tot het bijstellen van dit samenstel kunnen ertoe leiden dat het retentiemechanisme niet goed functioneert.
- Wees voorzichtig bij het hanteren van orthopedische voorwerpen met scherpe randen dat deze niet door de chirurgische handschoenen snijden.
- Behalve waar specifiek vermeld, raadt Howmedica Osteonics Corp. ten sterkste af een totale kniecomponent van een andere fabrikant te gebruiken in combinatie met welke totale kniecomponent van Howmedica Osteonics dan ook. Een dergelijke gebruik ontheft Howmedica Osteonics Corp. van aansprakelijkheid voor de prestatie van het resulterende implantaat met gemengde componenten.
- Howmedica Osteonics Corp. raadt ten sterkste af botschroeven van een andere fabrikant te gebruiken in combinatie met welke totale kniecomponent van Howmedica Osteonics dan ook, vanwege bestaande variaties in de configuraties van schroefkop en schroefzitting.

- Een totale kniecomponent kan met opzet voorzichtig verwijderd worden met chirurgische boren, dunne en smalle osteotomen en zorgvuldig toegepaste extractie.
- Van opzettelijke verwijdering van het kunststof tibia-inlegdeel na assemblage uit de metalen basisplaat gaat het kunststof inlegdeel kapot. Zorg bij het verwijderen van het inlegdeel dat de metalen basisplaat niet ingekerfd of ingesneden wordt.
- Stuur alle verpakkingen met defecten in de steriele barrière terug naar de leverancier. **Niet opnieuw steriliseren.**

Ongewenste effecten

- Hoewel het moeilijk is de levensduur van componenten van een totale knievervanging in te schatten, is deze eindig. Deze componenten zijn vervaardigd van lichaamsvreemde materialen die in het lichaam aangebracht worden voor mogelijk herstel van de mobiliteit of pijnvermindering. Omdat deze onderdelen echter beïnvloed worden door vele biologische, mechanische en fysisch-chemische, maar *in vivo* niet te evalueren factoren, kan niet worden verwacht dat de componenten voor onbepaalde tijd het activiteitsniveau en de belasting van normaal gezond bot kunnen doorstaan. De chirurg moet de patiënt uitleggen geen onrealistische verwachtingen te hebben van de levensduur van de prothese.
- Ten gevolge van verkeerde activiteiten van de patiënt, trauma of andere biomechanische oorzaken, kan de femur-, tibia- of patellaprothese geluxeerd raken.
- Het kan voorkomen dat totale kniecomponenten losraken. Vroegtijdig mechanisch losraken kan het resultaat zijn van onvoldoende initiële fixatie, latente infectie, voortijdige belasting van de prothese, verkeerd uitlijnen van de componenten of trauma. Losraken op een later tijdstip kan het gevolg zijn van trauma, infectie, biologische complicaties waaronder osteolyse, of mechanische problemen met daaropvolgend de mogelijkheid van boterosie en/of pijn.
- Bij een klein percentage van de patiënten zijn ten gevolge van materiaalmoeheid fracturen van totale kniecomponenten, waaronder tibia-, femur- en patellacomponenten, voorgekomen. Een breuk in een kniecomponent kan het gevolg zijn van onvoldoende ondersteuning van de component door het onderliggende bot of van slechte fixatie van de component.
- Er kan/kunnen zich perifere neuropathieën, zenuwletsel, circulatiestoornissen en heterotopische botvorming voordoen.
- Bij elke totale gewrichtsvervangende operatie kunnen ernstige complicaties optreden. Deze complicaties zijn onder meer, maar niet beperkt tot: aandoeningen van de tractus urogenitalis; gastro-intestinale stoornissen; vasculaire stoornissen, waaronder trombi; bronchopulmonale stoornissen, waaronder embolieën; myocardinfarct en overlijden.
- Slijtage van polyethyleencomponenten heeft zich voorgedaan en dit is in de literatuur in verband gebracht met botresorptie, losraken en infectie.
- Na gewrichtsvervanging is melding gemaakt van overgevoeligheidsreacties op metaal.
- Bijwerkingen kunnen een nieuwe operatie, revisie, artrodese van het betrokken gewricht en/of amputatie van de ledemaat noodzakelijk maken.
- Disbalans en/of laxiteit van de weke delen is in verband gebracht met slecht uitgelijnde componenten, wat kan leiden tot vroegtijdige slijtage en/of falen van het implantaat.
- Bij alle geïmplanteerde prothesen kan zich rond de protheseonderdelen asymptomatische gelokaliseerde progressieve botresorptie (osteolyse) voordoen als gevolg van een corpus alienumreactie op deeltjes afkomstig van cement, metaal, ultra-high molecular weight polyethylene (UHMWPE) en/of op keramisch materiaal. Deeltjes ontstaan door interactie tussen componenten onderling evenals tussen componenten en bot, voornamelijk ten gevolge van de slijtagemechanismen adhesie, afschuring, en materiaalmoeheid. Bovendien kunnen deeltjes ontstaan ten gevolge van slijtage van andere onderdelen. Osteolyse kan tot latere complicaties leiden, waaronder losraken, wat verwijderen en vervangen van de prothetische componenten noodzakelijk maakt.
- Het is bekend dat er bij normaal gebruik in de loop der tijd zeer kleine metaal- en polyethyleendeeltjes van de componenten kunnen afslijten. Hoewel het grootste deel van dit débris in het betreffende gewricht blijft (d.w.z. binnen het synovium) of gevangen wordt in omringend littekenweefsel, kunnen

microscopische deeltjes zich door het hele lichaam verspreiden (migreren). Er zijn momenteel onbeantwoorde vragen over débris en microscopische deeltjes die van deze componenten afkomstig kunnen zijn. Aangetoond is dat microscopische débrisdeeltjes zich door het hele lichaam kunnen verspreiden (migreren) en het is beschreven dat ze zich af en toe ophopen in lymfeklieren en andere delen van het lichaam. Hoewel er tot op heden geen significante medische complicaties zijn gerapporteerd als gevolg van deze deeltjes, zijn de migratie en/of ophoping ervan in het lichaam in de literatuur beschreven. Gezien het feit dat de patiënten in wie deze implantaten gebruikt worden nog onvoldoende lang gevolgd zijn, de patiënten momenteel jonger zijn en de implantaten steeds langer in het lichaam blijven, moet gezegd worden dat de eventuele effecten op lange termijn van deze deeltjes niet bekend zijn. Theoretisch zouden de langetermijneffecten onder meer kunnen zijn:

- **Kanker:** er is op dit moment wetenschappelijk geen verband aangetoond tussen metaal- of polyethyleendébris en kanker. De mogelijkheid kan echter niet worden uitgesloten.
- **Lymfadenopathie en ophoping in andere weefsels/organen:** er zijn een paar meldingen gemaakt van ophoping van slijtagedébris in lymfeklieren (proximaal en distaal). Hoewel er geen medische complicaties of ziekteprocessen zijn gerapporteerd als gevolg van deze ophopingen, moet het bestaan ervan worden erkend om ze te kunnen diagnosticeren en verwarring met verdachte laesies, carcinomateus of anderszins, te vermijden.
- **Systemische aandoeningen:** er is enige speculatie dat er een verband zou kunnen bestaan tussen migratie van débris en tot nog toe niet geïdentificeerde systemische effecten. Het is mogelijk dat er op een gegeven moment in de toekomst een bepaald langetermijneffect kan worden aangetoond, maar omdat er zeer weinig wetenschappelijke gegevens zijn die een verband suggereren tussen migratie van débris en systemische aandoeningen, wordt geloofd dat de voordelen van deze implantaten duidelijk opwegen tegen de mogelijke risico's van een dergelijk theoretisch effect op lange termijn.

Interactie met magnetische resonantiebeeldvorming

De veiligheid en compatibiliteit van het Triathlon kniesysteem in de MRI-omgeving is niet geëvalueerd. Het Triathlon kniesysteem is niet getest op verhitting en migratie onder invloed van MR.

Sterilisatie

- Deze totale kniecomponent is gesteriliseerd door gammastraling of waterstofperoxide-gasplasma. Raadpleeg het etiket op de verpakking voor de gebruikte sterilisatiemethode.
- Voordat deze wordt geopend, dient de verpakking van alle steriele producten gecontroleerd te worden op defecten in de steriele barrière. Indien een dergelijk defect wordt geconstateerd, moet verondersteld worden dat het product niet steriel is. Om het openen van een van de verpakkingslagen te vermijden voordat de component gebruikt gaat worden, zijn speciale pasprothesen verkrijgbaar.
- Voorzichtigheid is geboden om verontreiniging van de component te voorkomen. In geval van verontreiniging dient dit product weggegooid te worden.
- Indien een verpakking is geopend, maar het product is niet gebruikt, dan mag het product niet opnieuw gesteriliseerd worden en moet het weggegooid worden of teruggestuurd naar de leverancier.
- Het implantaat mag na de op het etiket vermelde uiterste gebruiksdatum niet meer gebruikt worden omdat de verpakking na deze datum niet meer gevalideerd is.
- Een implantaat bestemd voor eenmalig gebruik kan niet verwijderd en vervolgens opnieuw geïmplanteerd worden; de fysieke krachten waaraan het blootstaat bij deze handelingen kan de integriteit aantasten, de dimensies veranderen en/of de oppervlaktebewerking van het implantaat beschadigen. Ook kan de steriliteit van hergebruikte implantaten niet gewaarborgd worden wegens het ontbreken van gevalideerde reinigings- en hersterilisatieprocedures.

LET OP: **FEDERAL LAW (U.S.A.) VOLGENS DE AMERIKAANSE WETGEVING IS VERKOOP VAN DIT PRODUCT UITSLUITEND TOEGESTAAN AAN OF OP GEZAG VAN EEN GEREGISTREERDE ARTS.**

WAARSCHUWING: Componenten waarvan het etiket "Uitsluitend bestemd voor gecementeerde toepassing" vermeldt, dienen alleen met botcement te worden geïmplanteerd.

Stryker Corporation of haar divisies of andere gelieerde bedrijfsentiteiten zijn eigenaar van, gebruiken of hebben de volgende handelsmerken aangevraagd: Howmedica, Osteonics, Stryker, Triathlon. Alle andere handelsmerken of dienstmerken zijn handelsmerken of dienstmerken van hun respectievelijke eigenaars of houders.

Raadpleeg het productetiket voor de status van de CE-markering en de verantwoordelijke fabrikant. De CE-markering is alleen geldig als deze ook op het productetiket staat.

De onderstaande tabel bevat een lijst met afkortingen die gebruikt worden op de productetiketten van Howmedica Osteonics Corp. :

Term	Afkorting	Term	Afkorting
Alfacode	ALPH CDE	Hals	NK
Hoek	ANG	Offset	OFFST
Graden	DEG or °	Buitendiameter	OD
Diameter	DIA	Rechts	RT ▶
Extra diep	XDP	Schroefgaten	SCR HLS
Extra groot	XLGE	Zijde	SDE
Extra klein	XSM	Maat	SZE
Kop	HD	Klein	SM
Hoogte	HT	Standaard	STD
Binnendiameter	ID	Conus	TPR
Inlegdeel	INSR	Dikte	THKNS
Groot	LGE	Type	TYP
Links	◀ LFT	Met	W/
Lengte	LNTH	Zonder	W/O
Medium	MED		

Norsk

HOWMEDICA OSTEONICS' TRIATHLON TRITANIUM KNEALLOPLASTIKK IFU

Beskrivelse

Howmedica Osteonics Corp.'s totale knesystemer inkluderer Triathlon Tritanium baseplate som er fremstilt til bruk med Triathlon primære knesystemets femurkomponenter, tibiainnlegg, og patellarkomponenter til bruk med total rekonstruktiv erstatning av kneleddet. Spesifikke egenskaper for hver enkelte anordning står oppført på produktets etikett. Triathlon Tritanium baseplate er indisert for bruk både med og uten sement.

Femurkomponenter: Triathlon Tritanium baseplate er kompatibel med Triathlon korsbånds festedesign (CR), og korsbånds "sacrificing" design (stabilisert posteriørt – PS).

Tibiakomponenter: Triathlon Tritanium baseplate er kompatibel med Triathlon tibiainnlegg i et korsbånds festedesign (CR), stabilisert posteriørt (PS) design, og kondylare stabiliseringsdesign (CS). Tibiainnleggene leveres i en rekke tykkelser og tvangsgrader:

Merk: Triathlon Tritanium Baseplate er innpakket sammen med en impaktorpute. Impaktorputen skal bare brukes i løpet av tibiabaseplatens sammenpressingsskritt og må kasseres etter at sammenpressingen er fullført. Impaktorputen må ikke implanteres.

Patellakomponenter: Patella-gjenoppstående komponenter finnes tilgjengelig i asymmetriske og metallskjermede design fremstilt av bare plastikk. Bruk av en patellakomponent er valgfri. Triathlon Tritanium Baseplaten er kompatibel med alle Triathlon patellakomponentene.

Materialer

• ASTM F-75 kobolt kromlegering	Femurkomponenter
• ASTM F-90 kobolt kromlegering	Låseledning for tibiainnlegg
• ASTM F-1537 kobolt kromlegering	Femurskruer
• ASTM F-136 titaniumalloy	Tibiakomponenter
• ASTM F-67 CP titanium	Tibiakomponenter
• ASTM F-1185 kalsiumfosfat	Femurkomponenter, patellakomponenter
• ASTM F-648-ultrahøy molekylær vektpolyetylen	Tibiabærende innlegg, patellakomponenter

Indikasjoner

Indikasjoner for generell kne-artroplastikk (TKR):

- Smertefulle, invalidiserende leddsykdommer i kneet, som stammer fra: . ikke-betent degenererende leddsykdom (inkludert slitasjegikt, traumatisk gikt, eller avaskulær nekrose), reumatoid artritt eller post-traumatisk artritt.
- Post-traumatisk tap av kneleddskonfigurasjon og funksjon.
- Moderat varus-, valgus- eller fleksjonsdeformitet, hvor leddbåndsstrukturene kan gå tilbake til tilstrekkelig funksjon og stabilitet.
- Revisjon av tidligere mislykket knealloplastikk eller annet inngrep.
- Brudd på distalfemur og/eller proksimal tibia kan ikke stabiliseres ved hjelp av standard bruddbehandlingsteknikk.

Triathlon Tritanium baseplate er indisert til bruk både med og uten sement.

Tilleggsindikasjoner for posteriørt stabiliserte(PS) komponenter:

- Mangel på leddbåndsstabilitet som krever implantbærende overflategeometri med økt tvang.
- Posteriørt korsbånd som enten mangler eller ikke fungerer.
- Alvorlig anteposteriør ustabilitet ved kneleddet.

Kontraindikasjoner

- Alle aktive eller suspekte latente infeksjoner i eller rundt kneleddet.
- Fjerntliggende infeksjonssteder som kan forårsake hematogen smitte av implantatstedet,
- Enhver mental eller nevromuskulær lidelse som kan skape en uakseptabel risiko for mangel på protesestabilitet, protesefikseringssvikt eller komplikasjoner i løpet av postoperativ pleie.
- Benmateriale som er svekket på grunn av sykdom, infeksjon eller tidligere implantat, som ikke kan gi tilstrekkelig støtte og/eller fiksering av protesen.
- Umodent skjelett.
- Alvorlig mangel på stabilitet i kneleddet som en følge av manglende helhet og funksjon av sideordnede leddbånd.
- Fedme. En overvektig eller fet pasient kan fremstille belastning på protesen som kan føre til svikt av anordningens fiksering eller at selve anordningen svikter.

Forholdsregler

- Kirurgen må underrette pasienten både om rekonstruksjonens begrensninger og behovet for å beskytte implantatet mot full belastning helt til tilstrekkelig fiksering og helbredelse har funnet sted. Alt for mye aktivitet og traume som påvirker hofteerstatningen har vært involvert i svikt av rekonstruksjon gjennom løsrivelse, brudd og/eller slitasje på proteseimplantatet. Løsning av komponentene kan resultere i økning på slitasjepartikler, i tillegg til benskade, som vil bidra til at vellykket revisjonskirurgi vil bli vanskeligere.
- Kirurgen må underrette/advare pasienten om å begrense aktiviteter og beskytte det erstattede leddet mot urimelig belastning, samt å følge legens instrukser når det gjelder oppfølgingspleie og behandling.
- Kirurgene bør underette pasientene om de potensielle virkingene, inkludert anordningens begrensede holdbarhet og behovet for post-operativ beskyttelse av implantatet. Kirurgen bør advare pasientene om at anordningen ikke dupliserer et friskt ledds fleksibilitet, styrke, pålitelighet, eller holdbarhet, og at implantatet kan brekke eller skades som en følge av anstrengende aktivitet eller traume.
- Passende valg, anbringelse og fiksering av komponentene til knealloplastikk er kritisk viktige faktorer, som har innflytelse på implantatets holdbarhet. Slik som er tilfelle med alle proteseimplantater, påvirkes disse komponentenes holdbarhet av flere biologiske, biomekaniske og andre eksterne faktorer som begrenser deres holdbarhet. Som en følge av dette er det ytterst viktig å følge de indikasjoner, kontraindikasjoner, forholdsregler og advarsler som gjelder for produktet, med det formål å få mest ut av den potensielle holdbarheten.

Bruk og implantasjon

- De anbefalte prøvekomponentene bør brukes til å fastsette størrelse, prøvereduksjon og til evaluering av bevegelsesområdet. På denne måten kan man bevare de aktuelle implantaters helhet og deres sterile innpakking.
- Radiografiske sjablonger finnes til hjelp med den preoperative avgjørelsen av komponentstørrelse og stil.
- Forsiktighet må utvises for å fjerne benfliser, sementbiter fra ben og metallrester fra implantatområdet for å kunne redusere risiko for restebiter forårsaket av fremskyndet slitasje på implantatets leddoverflater.
- Kirurgiske protokoller fra Howmedica Osteonics Corp. gir ytterlige opplysninger om forskjellige typer inngrep.
- Se etiketten på produktet for opplysninger om spesifikk kompatibilitet. Rent generelt gjelder følgende:
  - Bruk bare PS femurkomponenter med PS tibiabæredeler.
  - Bruk bare CR femurkomponenter med CR tibiabæredeler.
  - Bruk bare PS eller CR femurkomponenter med CS tibiabæredeler.

Informasjon for pasienter.

- Kirurgen må underrette pasienten både om rekonstruksjonens begrensninger og behovet for å beskytte implantatet mot full belastning helt til tilstrekkelig fiksering og helbredelse har funnet sted. Alt for mye aktivitet og traume som påvirker hofteerstatningen har vært involvert i svikt av rekonstruksjon gjennom

løsrivelse, brudd og/eller slitasje på proteseimplantatet. Løsning av komponentene kan resultere i økning på slitasjepartikler, i tillegg til benskade, som vil bidra til at vellykket revisjonskirurgi vil bli vanskeligere.

- Kirurgen må underrette/advare pasienten om å begrense aktiviteter og beskytte det erstattede leddet mot urimelig belastning, samt å følge legens instrukser når det gjelder oppfølgingspleie og behandling.
- Pasienten må advares om forskjellige risikoer tilknyttet kirurgi og eventuelle bivirkninger. Pasienten må advares om at anordningen er ikke en erstatning av et normalt friskt ledd, at implantatet kan brekke eller skades som en følge av anstrengende aktivitet eller traume, og at anordningen har en begrenset levetid og vil eventuelt måtte erstattes i fremtiden.
- Transient bakteriemi kan forekomme i løpet av det daglige liv. Tannbehandling, endoskopisk undersøkelse og andre mindre kirurgiske inngrep har vært forbundet med transient bakteriemi. For å unngå infeksjon på implantatstedet, anbefales det at profylaktisk antibiotika brukes før og etter denne typen inngrep.

Advarsler

- Kasser alle skadde og feilhåndterte implantater.
- Et implantat må aldri brukes på nytt, selv om det virker som om det er uskadet.
- Impaktorputen må ikke implanteres. Impaktorputen må bare brukes i løpet av implantasjonsskrittet Må fjernes og kasseres umiddelbart etter implantasjonsprosessen.
- Polerte kontaktflater i bærestykket må ikke komme i kontakt med harde eller slipende flater.
- Bæreområdene må alltid være helt rene uten rester før montering finner sted.
- Konturering eller bøying av et implantat kan redusere slitestyrken og forårsake svikt under belastning.
- Innleggets retensjonstråd av metall må ikke håndteres eller fjernes, da den er ytterst viktig for samlingens sikkerhet. Kasser alle tibiainnlegg hvor retensjonstråden ser ut som om den er skadet eller behandlet feil. Hvis man utfører endringer i samlingen, kan man risikere at retensjonsmekanismen kommer til å fungere feil.
- Omhu bør utvises for å unngå å skjære gjennom de kirurgiske hanskene under håndteringen av alle ortopediske anordninger med skarpe kanter.
- Bortsett fra der hvor det er avmerket, fraråder Howmedica Osteonics Corp.'s på det sterkeste at knealloplastikk-komponenter av et annet fabrikat brukes i forbindelse med alle knealloplastikk-komponenter fra Howmedica Osteonics. Denne typen bruk vil oppheve Howmedica Osteonics Corp.'s ansvar for arbeidsprestasjonen som oppstår gjennom bruk av det resulterende oppståtte blandede komponentimplantat.
- Howmedica Osteonics Corp. fraråder på det sterkeste at man bruker benskruer av et annet fabrikat i tilknytning til alle knealloplastikk-komponenter fra Howmedica Osteonics på grunn av variasjoner mellom skruhodet og skruesetekonfigurasjoner
- En knealloplastikk-komponent kan fjernes med overlegg gjennom forsiktig bruk av skjæreborr, tynne og smale osteotomer og forsiktig uttrekningskraft.
- Når et tibiainnlegg av plastikk fjernes med vilje, etter at den er samlet i et metalltray, ødelegges plastinnlegget. Vær forsiktig slik at tibialtrayets overflate ikke utsettes for skrammer eller hakk, mens innlegget fjernes.
- Alle pakker med feil i den sterile barrieren må returneres til leverandøren. **Må ikke gjensteriliseres.**

Bivirkninger

- Selv om den forventede holdbarheten tilknyttet komponentene i hofteleddsalloplastikk er vanskelig å vurdere, er den imidlertid begrenset. Disse komponentene er laget av utlandske materialer som plasseres inne i kroppen for potensiell gjenoppbygging av bevegelighet eller reduksjon av smerte. Imidlertid kan komponentene – som på grunn av de mange biologiske, mekaniske og fysiokjemiske faktorene som har innflytelse på disse anordningene, men som ikke kan vurderes *in vivo*, ikke forventes å kunne motstå de samme aktivitetsnivåer og belastninger som normale, sunne ben for alltid. Kirurgene bør advare pasientene mot å ha urealistiske forventninger tilknyttet anordningens levetid.

- Forskyvning av femur-, tibia- eller patellaprotesen kan forekomme forårsaket av pasientens upassende aktivitet, traume eller andre biomekaniske faktorer.
- Løsrivelse av komponenter i knealloplastikken kan finne sted. Tidlig mekanisk løsrivelse kan forårsakes av utilstrekkelig opprinnelig fiksering, latent infeksjon, for tidlig belastning av protesen, feil komponenttilpasning eller traume. Sen løsrivelse kan resultere fra traume, infeksjon, biologiske komplikasjoner, inkludert osteolyse eller mekaniske problemer med etterfølgende mulighet for benerosjon og/eller smerte.
- I en liten prosentdel av tilfeller har det forekommet slitefrakturer i knealloplastikk-komponentene, inkludert tibia-, femur- og patellakomponenter. Fraktur av en knekomponent kan finne sted på grunn av utilstrekkelig komponentstøtte fra det underliggende benet eller dårlig komponentfiksering.
- Perifere nevropatier, nerveskade, svekket kretsløp og heterotopisk bendannelse kan forekomme.
- Alvorlige komplikasjoner kan assosieres med enhver totale leddalloplastikkoperasjon. Disse komplikasjonene inkluderer, men er ikke begrenset til: urogenitale lidelser, gastrointestinale lidelser, vaskulære lidelser, bl.a. trombose, bronkopulmonale lidelser, bl.a. emboli, myokardieinfarkt eller dødsfall.
- Forekomster av slitasje på polyetylenkomponenter har funnet sted, og rapporter i litteraturen setter denne forekomsten i forbindelse med benresorpsjon, løsrivelse og infeksjon.
- Det finnes rapporter om overfølsomhet mot metall etter leddalloplastikk.
- Bivirkninger kan eventuelt nødvendiggjøre en ny operasjon, revisjon, artrodese i det leddet som er involvert, og/eller amputering av lemmet.
- Ubalanse i mykdelene og/eller slapphet har blitt satt i sammenheng med feilstilling av komponentene, som kan resultere i tidlig slitasje og/eller implantatsvikt.
- I likhet med alle implantatanordninger, kan det forekomme asymptomatisk, lokalisert, progressiv benresorpsjon (osteolyse) omkring protesekomponentene som følge av fremmedlegemereaksjon på partikler av sement, metall, polyetylen med ultrahøy molekylvekt (UHMWPE) og/eller keramikk. Det dannes partikler ved gjensidig påvirkning mellom komponentene, samt mellom komponenter og ben, først og fremst gjennom mekanismer som f.eks. adhesjon, abrasjon og slitasje. Sekundært kan partikler også dannes gjennom tredjepartslitasje. Osteolyse kan resultere i fremtidige komplikasjoner, bl. a. løsrivelse, hvor det blir nødvendig å fjerne og skifte ut protesekomponenter.
- Det er kjent at meget små partikler fra metall- og polyetylenkomponenter kan, ved normal bruk og med tiden, kan bli avkastet fra komponentene. Selv om mesteparten av disse restene oppbevares i det relevante leddet, (for eksempel i synovium) eller blir oppfanget av omgivende arrvev, kan mikroskopiske partikler eventuelt bevege seg eller migrere utenfor leddet til forskjellige deler av kroppen. For tiden finnes det ubesvarte spørsmål berørende restebiter og mikroskopiske partikler som kan genereres fra disse komponentene. Det har vist seg at mikroskopiske restebitpartikler kan spre seg (migrere) gjennom kroppen og har til enkelte tider blitt beskrevet som å ha oppsamlet seg i lymfeknutene og andre deler av kroppen. Selv om det ikke er blitt innrapportert noen betydningsfulle helbredsmessige komplikasjoner som resultat av disse partiklene, har deres bevegelse og/eller oppsamling i kroppen blitt beskrevet i litteraturen. Tatt i betraktning det utilstrekkelige tidsrommet hvor pasientene er observert, og den kjensgjerning at disse anordningene nå blir brukt i yngre pasienter og forblir i kroppen i stadig lengre tidsperioder, må man si at eventuelle langtidsvirkninger av disse partiklene er ukjent. De teoriserte langtidsvirkningene inkluderer:
  - **Kreft:** For øyeblikket finnes det ingen vitenskapelige bevis som forbinder metall- eller polyentylenrester med kreft. Imidlertid kan man ikke utelukke denne muligheten.
  - **Lymfeknutesvulst og oppsamling i andre vev/organer.** Det har forekommet noen få rapporter vedrørende oppsamling av slitasjerester i lymfeknuter (nær- og fjerntliggende). Selv om det ikke er rapportert noen helbredsmessige komplikasjoner eller sykdomsforløp som stammer fra disse oppsamlingene, bør deres tilstedeværelse anerkjennes for å forenkle diagnosen og unngå forvirring i tilknytning til eventuelle lesjoner, hvorvidt disse er ondartede eller ikke.
  - **Systemisk sykdom:** Det har vært noe spekulasjon tilknyttet hvorvidt det kan være en forbindelse mellom migrering av rester og visse ikke-identifiserte systemiske virkninger. Det er mulig at noen langtidsvirkninger vil kunne demonstreres på et tidspunkt i fremtiden, men siden det finnes meget begrenset vitenskapelig data som tyder på en forbindelse mellom flytning av rester og systemiske

virkninger, mener man at fordelen ved disse anordningene klart oppveier den potensielle risikoen for denne typen teoretisk langtidsvirkning.

Samhandling med Magnetic Resonance Imaging

Triathlon knesystemen har ikke blitt evaluert for sikkerhet og kompatibilitet i MR miljøet. Triatholon knealloplastikksystemene har ikke blitt evaluert for sikkerhet og kompatibilitet i MR miljøet.

Sterilisering

- Denne knekomponenten har blitt sterilisert med gammastråling eller hydrogenperoksid gassplasma. Vi henviser til pakkens etikett for sterilseringsmetoden.
- Innpakningen av alle sterile produkter må undersøkes for feil i den sterile barrieren før den åpnes. Hvis man finner feil, skal produktet anses for å være usterilt. Det finnes spesielle prøveproteser, slik at det ikke er nødvendig å åpne noen som helst del av den sterile pakken før komponenten skal tas i bruk.
- Forsiktighet må utvises for å unngå kontaminasjon av komponentene. Hvis produktet blir kontaminert, skal det kasseres.
- Hvis pakken er åpnet, men produktet ikke har vært brukt, må komponenten ikke resteriliseres og må kasseres eller sendes tilbake til leverandøren.
- Anordningen må ikke brukes etter utløpsdatoen på etiketten da innpakningen ikker er validert etter den datoen.
- Anordninger til engangsbruk kan ikke eksplanteres og deretter implanteres på nytt da de fysiske kreftene som brukes av disse handlingene kan kompromittere anordningenes fysiske integritet, dimensjoner og/ eller overflatebehandlinger. I tillegg kan man ikke være sikker på at de anordningene som brukes på nytt forblir sterile da rengjøring og re-sterilisering ikke har blitt bekreftet.

OBS! **AMERIKANSK LOV (USA) BEGRENSER DENNE ANORDNINGN TIL SALG AV ELLER PÅ ANBEFALING AV EN LEGE.**

ADVARSEL: Komponenter merket "Bare til bruk med sement" må bare implanteres med bensement.

Henvis til produktetiketten for CE merkestatus og lovlig fabrikant. CE merket er bare gyldig hvis det også finnes på produktetiketten.

Den følgende tabellen inneholder en liste over de forkortelsene som brukes på Howmedica Osteonics Corp.'s produktetiketter:

Betegnelse	Forkortelse	Betegnelse	Forkortelse
Alfakode	ALPH CDE	Hals	NK
Vinkel	ANG	Offset	OFFST
Grader	DEG or °	Utvendig diameter	OD
Diameter	DIA	Høyre	RT ▶
Ekstra dyp	XDP	Skruehull	SCR HLS
Ekstra stor	XLGE	Side	SDE
Ekstra liten	XSM	Størrelse	SZE
Hode	HD	Liten	SM
Høyde	HT	Standard	STD
Innvendig diameter	ID	Konusform	TPR
Innlegg	INSR	Tykkelse	THKNS
Stor	LGE	Type	TYP
Venstre	◀ LFT	Med	W/
Lengde	LNTH	Uten	W/O
Medium	MED		

Język polski

CAŁKOWITA ENDOPROTEZA STAWU KOLANOWEGO TRIATHLON TRITANIUM HOWMEDICA OSTEONICS – INSTRUKCJA UŻYTKOWANIA

Opis

W skład systemów całkowitej endoprotezy firmy Howmedica Osteonics Corp., stosowanych do całkowitej alloplastyki stawu kolanowego wchodzą: płytka Triathlon Tritanium przeznaczona do użytku z komponentami udowymi systemu endoprotezy stawu kolanowego Triathlon, wkładki piszczelowe i komponenty rzepkowe. Charakterystykę każdego produktu zamieszczono na jego etykiecie. Płytka Triathlon Tritanium jest przeznaczona zarówno do zastosowań cementowych, jak i bezcementowych.

Komponenty udowe: Płytka Triathlon jest kompatybilna z systemami Triathlon przeznaczonymi do zabiegów z zachowaniem więzadła krzyżowego (CR) oraz zabiegów z wycięciem więzadła krzyżowego (tylnie stabilizowanymi – PS).

Komponenty piszczelowe: Płytka Triathlon Tritanium jest kompatybilna z wkładkami piszczelowymi Triathlon stosowanymi w zabiegach z zachowaniem więzadła krzyżowego (CR), w zabiegach z tylną stabilizacją (PS) oraz zabiegach ze stabilizacją kłykciową (CS). Dostępne są wkładki piszczelowe o różnych grubościach i mające różne typy ograniczników.

Uwaga: Płytka Triathlon Tritanium znajduje się w jednym opakowaniu z podkładką podbijaka. Podkładka podbijaka przeznaczona jest do użytku wyłącznie na etapie osadzania płytki piszczelowej i po zakończeniu tego etapu komponent ten należy wyrzucić. Podkładka podbijaka nie jest przeznaczona do implantacji.

Komponenty rzepkowe: Komponenty rzepkowe dostępne są jako symetryczne i asymetryczne wykonane całkowicie z plastiku oraz ze wzmocnieniem metalowym. Użycie komponentu rzepkowego jest opcjonalne. Płytka Triathlon Tritanium jest kompatybilna ze wszystkimi komponentami rzepkowymi Triathlon.

Materiały

• Stop kobaltowo-chromowy, zgodny z normą ASTM F-75	Komponenty udowe
• Stop kobaltowo-chromowy, zgodny z normą ASTM F-90	Drut blokujący do wkładek piszczelowych
• Stop kobaltowo-chromowy, zgodny z normą ASTM F-1537	Kołki udowe
• Stop tytanowy zgodny z normą ASTM F-136	Komponenty piszczelowe
• Chemicznie czysty tytan, zgodny z normą ASTM F-67	Komponenty piszczelowe
• Fosforan wapnia zgodny z normą ASTM F-1185	Komponenty udowe, komponenty rzepkowe
• Polietylen o bardzo dużej masie cząsteczkowej zgodny z normą ASTM F-648	Piszczelowe wkładki nośne, komponenty rzepkowe

Wskazania

Ogólne wskazówki dotyczące całkowitej alloplastyki stawu kolanowego (TKR):

- Choroba stawu kolanowego powodująca ból i niepełnosprawność, mająca następujące podłoże: zmiany zwyrodnieniowe pochodzenia niezapalnego (w tym osteoartroza, pourazowe zapalenie stawu lub martwica niedokrwienna), reumatoidalne lub pourazowe zapalenie stawu.
- Pourazowe naruszenie prawidłowej budowy i utrata czynności stawu kolanowego.

- Umiarkowana koślawość, szpotawość lub deformacja zgięciowa stawu, w przypadku której właściwa stabilność struktury więzadeł może zostać przywrócona.
- Operacja rewizyjna wcześniejszej nieudanej operacji wymiany stawu kolanowego lub innego zabiegu.
- Złamanie dystalnej części kości udowej i/lub proksymalnej części kości piszczelowej, którego mnie można ustabilizować przy zastosowaniu standardowych metod postępowania ze złamaniami.

Płytka Triathlon Tritanium przeznaczona jest zarówno do użytku bezcementowego jak i cementowego.

Dodatkowe wskazania dotyczące komponentów ze stabilizacją tylną (PS):

- Niestabilność wiązadeł wymagająca zastosowania implantu o powierzchni nośnej mającej geometrię zapewniającą zwiększone ograniczenie ruchów.
- Brak lub niewydolność więzadła krzyżowego.
- Znaczna przednio-tylna niestabilność stawu kolanowego.

Przeciwwskazania

- Dowolna aktywna infekcja stawu kolanowego lub jego okolicy, bądź podejrzenie utajonej infekcji.
- Odległe ogniska infekcji (które mogą szerzyć się drogą krwi do miejsca, gdzie wszczepiony jest implant).
- Jakiekolwiek zaburzenia psychiczne lub nerwowo-mięśniowe, które mogłyby wpłynąć na podwyższenie ryzyka niestabilności lub obluzowania endoprotezy do poziomu nieakceptowanego, bądź spowodować komplikacje w okresie rekonwalescencji pooperacyjnej.
- Osłabienie łoża kostnego na skutek zmian chorobowych, zakażenia albo uprzedniej implantacji, uniemożliwiające właściwe podparcie i (lub) osadzenie protezy.
- Niedojrzałość kośćca.
- Znaczna niestabilność stawu kolanowego, będąca wynikiem braku integralności lub utraty czynności więzadła pobocznego.
- Otyłość. Pacjenci otyli lub mający nadwagę mogą przeciążać protezę, co w efekcie może doprowadzić do jej obluzowania lub niesprawności.

Środki ostrożności

- Chirurdzy muszą poinformować pacjentów o ograniczeniach związanych z rekonstrukcją i o konieczności ochrony implantu przed pełnym obciążaniem do czasu osiągnięcia odpowiedniego zamocowania i zakończenia procesu gojenia. Na niepowodzenie operacji rekonstrukcji ma wpływ nadmierna aktywność i urazy oddziaływujące na protezę, głównie poprzez obluzowywanie, złamania i/lub zużywanie się implantu. Obluzowywanie komponentów może doprowadzić do wzrostu wytwarzania drobin w wyniku zużywania, jak również do uszkodzenia kości, co może utrudniać osiągnięcie pomyślnego wyniku operacji rewizyjnej.
- Lekarz powinien ostrzec pacjentów o konieczności ograniczenia aktywności i zapobiegania nieuzasadnionemu obciążeniu wymienionego stawu oraz przestrzegania zaleceń lekarza w zakresie opieki i leczenia pooperacyjnego.
- Chirurdzy powinni ostrzegać pacjentów o potencjalnych skutkach ubocznych, w tym o ograniczonym okresie trwałości endoprotezy oraz konieczności ochrony implantu w okresie pooperacyjnym. Chirurg powinien poinformować pacjentów, iż urządzenie nie posiada elastyczności, siły, niezawodności i wytrzymałości normalnego, zdrowego stawu i że implant może pęknąć lub ulec zniszczeniu w wyniku obciążającej go aktywności lub urazu.
- Odpowiedni dobór, właściwe umieszczenie i zamocowanie komponentów całkowitej endoprotezy stawu kolanowego są czynnikami krytycznymi określającymi okres trwałości klinicznej implantu. Tak jak w przypadku wszystkich sztucznych implantów, trwałość tych komponentów zależy od wielu biologicznych, biomechanicznych i innych zewnętrznych czynników, które ograniczają ich okres trwałości klinicznej. W związku z tym, ścisłe przestrzeganie wskazań, respektowanie przeciwwskazań i ostrzeżeń oraz podejmowanie środków ostrożności związanych ze stosowaniem produktu jest istotne dla maksymalnego przedłużenia tego okresu.

Użytkowanie i wszczepianie

- W celu wyznaczenia rozmiarów, nastawienia próbnego i określenia zakresu ruchów należy skorzystać z zalecanych przyrządów pomiarowych, elementów wzorcowych i próbnych. Dzięki temu właściwa proteza przeznaczona do implantacji pozostanie w postaci nienaruszonej i sterylność opakowania zostanie zachowana.
- W charakterze pomocy w dopasowywaniu rozmiarów i rodzaju komponentów przed operacją dostępne są wzorniki radiograficzne.
- Aby zmniejszyć ryzyko przedwczesnego zużycia powierzchni stawowych implantu spowodowanego obecnością zanieczyszczeń, należy dokładnie usunąć z miejsca implantacji odłamki kości, fragmenty cementu kostnego i cząstki metalu.
- Dodatkowe informacje dotyczące stosowanych procedur zamieszczone są w protokołach chirurgicznych firmy Howmedica Osteonics Corp.
- Informacje dotyczące kompatybilności produktu zostały zamieszczone na jego etykiecie. Na ogół obowiązują następujące zasady:
  - Komponenty udowe PS należy używać wyłącznie z piszczelowymi komponentami nośnymi PS
  - Komponenty udowe CR należy używać wyłącznie z komponetami piszczelowymi CR
  - Z piszczelowymi komponentami nośnymi CS można używać zarówno komponentów udowych PS jak i CR

Informacje dla pacjentów

- Chirurg musi poinformować pacjenta o ograniczeniach związanych z rekonstrukcją i o konieczności ochrony implantu przed pełnym obciążaniem, aż do czasu osiągnięcia odpowiedniego zamocowania i zakończenia procesu gojenia. Na niepowodzenie operacji rekonstrukcji ma wpływ nadmierna aktywność i urazy oddziaływujące na protezę, głównie poprzez obluzowywanie, złamania i/lub zużywanie się implantu. Obluzowywanie komponentów może doprowadzić do wzrostu wytwarzania drobin w wyniku zużywania, jak również do uszkodzenia kości, co może utrudniać osiągnięcie pomyślnego wyniku operacji rewizyjnej.
- Chirurg powinien pouczyć pacjenta, aby ograniczać aktywność i zapobiegać nieuzasadnionemu obciążaniu wymienionego stawu oraz przestrzegać zaleceń lekarza dotyczących opieki i leczenia pooperacyjnego.
- Chirurg powinien poinformować pacjenta o ryzyku operacyjnym i o możliwych działaniach niepożądanych. Chirurg powinien uświadomić pacjentowi, iż urządzenie nie zastąpi normalnego, zdrowego stawu i że implant może pęknąć lub ulec zniszczeniu w wyniku obciążającej go aktywności lub urazu oraz o tym, iż urządzenie ma ograniczony okres trwałości klinicznej i w przyszłości może być wymagana jego wymiana.
- W życiu codziennym należy liczyć się z możliwością wystąpienia przejściowej bakteriemii. Przejściową bakteriemię mogą również spowodować zabiegi dentystyczne, badania endoskopowe i inne drobne zabiegi chirurgiczne. Przed wykonaniem każdego zabiegu zaleca się zastosowanie profilaktyki antybiotykowej dla zapobieżenia infekcji w miejscu wszczepiania implantu.

Ostrzeżenia

- Należy wyrzucić wszystkie protezy uszkodzone i te, z którymi niewłaściwie się obchodzono.
- Nigdy nie używać protezy ponownie, nawet w przypadku, gdy wydaje się nieuszkodzona.
- Nie wszczepiać podkładki podbijaka. Wkładka podbijaka przeznaczona jest do użytku wyłącznie na etapie osadzania płytki piszczelowej. Należy ją usunąć i wyrzucić natychmiast po zakończeniu procesu osadzania.
- Polerowane powierzchnie nośne nie mogą stykać się z powierzchniami twardymi lub ściernymi.
- Przed zamocowaniem należy koniecznie upewnić się, że powierzchnie nośne są czyste i wolne od drobin.
- Konturowanie lub gięcie protezy może zmniejszyć jej wytrzymałość zmęczeniową i przyczynić się do jej uszkodzenia przy obciążaniu.

- Nie powinno się manipulować metalowym drutem zabezpieczającym wkładki ani go wyjmować, ponieważ jest to kluczowy element zabezpieczający zestawu. Należy wyrzucić każdą piszczelową wkładkę nośną, której metalowy drut zabezpieczający wydaje się być uszkodzony lub istnieją oznaki, że niewłaściwie się z nim obchodzono. Nieumiejętne manipulowanie zmontowanym zestawem może doprowadzić do niewłaściwego działania mechanizmu zabezpieczającego.
- Należy uważać, aby podczas manipulowania jakimkolwiek ostro zakończonym narzędziem ortopedycznym nie spowodować przecięcia rękawic chirurgicznych.
- Jeśli nie określono inaczej, firma Howmedica Osteonics Corp. zdecydowanie przestrzega przed stosowaniem wraz z komponentami całkowitej endoprotezy stawu kolanowego Howmedica Osteonics komponentów całkowitej endoprotezy stawu kolanowego wyprodukowanych przez innego producenta. Użycie takie spowoduje uchylenie odpowiedzialności ze strony Howmedica Osteonics Corp. za prawidłowe działanie implantu składającego się z komponentów wyprodukowanych przez różnych producentów.
- Firma Howmedica Osteonics zdecydowanie przestrzega przed używaniem śrub kostnych wyprodukowanych przez innych producentów łącznie z jakimikolwiek komponentami całkowitej endoprotezy stawu kolanowego firmy Howmedica Osteonics. Powodem tego jest różnica ukształtowania łba śruby i gniazda.
- Komponent całkowitej endoprotezy stawu kolanowego można celowo usunąć, używając w ostrożny sposób wierteł tnących, cienkich i wąskich osteotomów oraz rozważnie dobierając siłę ekstrakcji.
- Umyślе wyjęcie plastikowej wkładki piszczelowej po jej zamontowaniu w metalowej płytce piszczelowej spowoduje zniszczenie tej wkładki. Należy uważać, aby podczas wyjmowania wkładki nie wyszczerbić ani nie nadłamać powierzchni płytki piszczelowej.
- Należy zwrócić dostawcy wszystkie opakowania z wadami osłony zabezpieczającej sterylność. **Nie sterylizować powtórnie.**

Działania niepożądane

- Przewidywany okres trwałości klinicznej komponentów całkowitej endoprotezy stawu kolanowego jest trudny do oceny, ale należy mieć świadomość, że jest on ograniczony. Zbudowane z materiałów obcych komponenty endoprotezy umieszczane są w ciele pacjenta w celu przywrócenia sprawności ruchowej lub zmniejszenia dolegliwości bólowych. Nie należy jednak oczekiwać, że komponenty endoprotezy będą w sposób nieograniczony znosić poziom aktywności i obciążenia na poziomie normalnej, zdrowej kości. Jest to spowodowane trudnym do określenia w warunkach *in vivo* wpływem wielu biologicznych, mechanicznych i fizykochemicznych czynników, które oddziałują na komponenty. Chirurdzy powinni uświadomić pacjentom, że okres trwałości klinicznej endoprotezy jest ograniczony, aby nie mieli oni nierealistycznych oczekiwań.
- Niedostosowany do nowych warunków poziom aktywności pacjenta, uraz lub inne czynniki biomechaniczne mogą spowodować przemieszczenie komponentu udowego, piszczelowego lub rzepkowego.
- Może nastąpić poluzowanie komponentów całkowitej endoprotezy stawu kolanowego. Mechaniczne obluzowanie występujące we wczesnym okresie może być wynikiem niedostatecznego początkowego zamocowania, utajonej infekcji, przedwczesnego obciążania protezy, niewłaściwego ustawienia komponentu lub urazu. Przyczyną późnego poluzowania może być uraz, infekcja, powikłania natury biologicznej, w tym osteoliza lub problemy mechaniczne. W następstwie tego może powstać nadżerka kostna i/lub mogą wystąpić bóle.
- Złamanie zmęczeniowe komponentów całkowitej endoprotezy stawu kolanowego, w tym komponentów piszczelowych, udowych i rzepkowych, odnotowano w niewielkim procencie przypadków. Złamanie komponentu endoprotezy stawu kolanowego może zostać spowodowane nieodpowiednim podparciem komponentu przez tkankę kostną leżącą głębiej lub jego słabym zamocowaniem.
- Mogą wystąpić także: neuropatia obwodowa, uszkodzenie nerwu, upośledzenie krążenia i tworzenie heterotopowych ognisk kostnienia.
- W przypadku każdego zabiegu całkowitej alloplastyki stawu należy liczyć się z możliwością poważnych powikłań. Powikłania te to między innymi: zaburzenia układu moczowo-płciowego, zaburzenia układu pokarmowego, zaburzenia naczyniowe włącznie z tworzeniem się skrzeplin, choroby oskrzelowo-płucne, w tym tworzenie się czopów zatorowych, zawał mięśnia sercowego lub zgon.

- Zaobserwowano także zjawisko zużywania komponentów polietylenowych. Według danych literaturowych jest to związane z resorpcją kości, obluzowywaniem i infekcją.
- Po wymianie stawu odnotowano też oznaki wrażliwości na metal.
- Działania niepożądane mogą powodować konieczność powtórnej operacji, operacji rewizyjnej, artrodezy stawu kolanowego i (lub) amputacji kończyny.
- Niestabilność i/lub zwiotczenie tkanki miękkiej zostało powiązane z niewłaściwym ustawieniem komponentów, które może spowodować przedwczesne zużycie i/lub uszkodzenie implantu.
- W przypadku wszystkich wszczepów syntetycznych w okolicy komponentów protezy może wystąpić bezobjawowa, umiejscowiona, postępująca resorpcja kości (osteoliza). Zjawisko to jest wynikiem reakcji na ciała obce, którymi są drobiny cementu, metalu, polietylenu o bardzo dużej masie cząsteczkowej (UHMWPE) i/lub materiał ceramiczny. Drobiny powstają wskutek oddziaływania między samymi komponentami, a także pomiędzy komponentami a kością. Jest to głównie następstwem zużywania w wyniku adhezji, ścierania i zmęczenia materiału. Dodatkowo powstawanie drobin może wynikać ze zużywania powodowanego przez ciała trzecie. Osteoliza kości może prowadzić do dalszych powikłań, włączając obluzowanie, w wyniku czego konieczne może okazać się usunięcie i wymiana komponentów protezy.
- Jest rzeczą wiadomą, że podczas normalnego użytkowania i w miarę upływu czasu z komponentów metalowych i polietylenowych mogą być ścierane bardzo małe drobiny. Chociaż większość z tych drobin pozostaje w stawie poddanym zabiegowi (w błonie maziowej) lub zostaje uwięziona w otaczającej tkance bliznowatej, to jednak mikroskopijnej wielkości cząstki mogą przemieszczać się (migrować) poza obszar stawu do innych części ciała. Obecnie nie ma jeszcze odpowiedzi na wszystkie pytania dotyczące zanieczyszczeń i mikroskopijnych cząstek, które mogą wydzielać się z tych komponentów. Mikroskopijnej wielkości cząstki mogą rozsiewać się (migrować) po ciele i sporadycznie, jak zaobserwowano, gromadzić się w węzłach chłonnych i innych częściach ciała. Pomimo, że dotychczas nie odnotowano żadnych komplikacji medycznych spowodowanych tymi cząstkami, niemniej ich migracja i (lub) akumulacja w ciele została opisana w literaturze. Biorąc pod uwagę niewystarczająco długi okres obserwacji pacjentów, którym wszczepiono endoprotezy, oraz fakt, że obecnie produkty te stosowane są u młodszych pacjentów i pozostają w ciele przez dłuższy czas, należy zaznaczyć, że efekty długofalowe, jeśli w ogóle występują, są nieznane. Teoretycznie możliwe efekty długoterminowe obejmują:
  - **Rak:** Obecnie nie ma dowodu naukowego na związek między obecnością i migracją drobin metalowych lub polietylenowych a zapadalnością na raka. Jednakże takiej możliwości nie można wykluczyć.
  - **Uogólnione powiększenie węzłów chłonnych i akumulacja w innych tkankach lub narządach:** Odnotowano kilka przypadków akumulacji w węzłach chłonnych (proksymalnych i dystalnych) drobin powstałych w wyniku zużycia materiałów. Chociaż nie zaobserwowano żadnych komplikacji natury medycznej ani procesów chorobowych będących wynikiem tej akumulacji, to jednak obecność drobin powinno się rozpoznać w celu ułatwienia diagnozy i uniknięcia pomyłki z podejrzanymi zmianami, zmianami nowotworowymi lub jakimikolwiek innymi.
  - **Choroby układowe:** Przypuszcza się, że może istnieć związek między migracją drobin a występowaniem dotychczas nie zidentyfikowanych efektów natury układowej. Możliwe jest, że niektóre efekty długoterminowe mogą objawić się w pewnym stopniu dopiero w przyszłości. Niewiele jest danych naukowych wskazujących na związek między migracją drobin i chorobami układowymi. Dlatego też przypuszcza się, że korzyści płynące z zastosowania produktu przeważą wyraźnie nad potencjalnym ryzykiem wystąpienia jakichkolwiek przewidywanych teoretycznie efektów długofalowych.

Interakcja z obrazowaniem metodą rezonansu magnetycznego

System do alloplastyki stawu kolanowego Triathlon nie został oceniony pod względem bezpieczeństwa i kompatybilności w środowisku rezonansu magnetycznego. System do alloplastyki stawu kolanowego Triathlon nie został przetestowany pod względem nagrzewania się i przemieszczania w środowisku rezonansu magnetycznego.

Sterylizacja

- Niniejszy komponent do całkowitej alloplastyki stawu kolanowego został poddany sterylizacji promieniowaniem gamma lub sterylizacji plazmowej nadtlenkiem wodoru. Informacje na temat metody sterylizacji zostały zamieszczone na etykiecie opakowania.

- Przed otwarciem należy sprawdzić opakowania wszystkich sterylnych produktów pod kątem istnienia uszkodzeń osłony zabezpieczającej sterylność. W przypadku obecności jakichkolwiek wad, produkt należy uznać za niesterylny. W celu uniknięcia konieczności otwierania jakiejkolwiek części sterylnego opakowania przed docelowym użyciem komponentu, dostępne są specjalne protezy próbne.
- Należy uważać, aby nie zanieczyścić ani nie skazić komponentu. W przypadku zanieczyszczenia produkt ten należy wyrzucić.
- Po otwarciu opakowania, nawet jeśli produkt nie był używany, komponentu nie wolno poddawać ponownej sterylizacji i należy go wyrzucić lub zwrócić dostawcy.
- Urządzenia nie należy używać po wygaśnięciu podanej na etykiecie daty ważności, ponieważ opakowanie nie zostało zatwierdzone dla okresu wykraczającego poza tę datę.
- Urządzeń jednorazowego użytku nie można usunąć, a następnie ponownie implantować, ponieważ siły wywierane wskutek wykonywania tych procedur mogą wywrzeć negatywny wpływ na integralność fizyczną, wymiary i/lub wykończenie powierzchni urządzenia. Ponadto w przypadku ponownie użytych urządzeń nie można zapewnić sterylności, ponieważ procedury czyszczenia i ponownej sterylizacji nie zostały sprawdzone.

UWAGA: **PRAWO FEDERALNE USA DOPUSZCZA SPRZEDAŻ TEGO URZĄDZENIA WYŁĄCZNIE PRZEZ LUB NA ZLECENIE LEKARZA.**

OSTRZEŻENIE: Komponenty oznaczone jako przeznaczone „Wyłącznie do użytku cementowego" należy implantować tylko z użyciem cementu kostnego.

Informacje o statusie znaku CE i legalnym producencie podano na etykiecie produktu. Znak CE jest ważny tylko wtedy, gdy znajduje się również na etykiecie produktu.

Zamieszczona poniżej tabela zawiera wykaz skrótów używanych na etykietach produktów firmy Howmedica Osteonics Corp. :

Termin	Skrót	Termin	Skrót
Kod alfa	ALPH CDE	Szyja/ szyjka	NK
Kąt	ANG	Wyrównanie	OFFST
Stopień	DEG or °	Średnica zewnętrzna	OD
Średnica	DIA	Prawa	RT ▶
X Głęboki	XDP	Otwory na śruby	SCR HLS
XL	XLGE	Boczne	SDE
XS	XSM	Rozmiar	SZE
Głowa	HD	Mały (S)	SM
Wysokość	HT	Standard	STD
Średnica wewnętrzna	ID	Zwężenie	TPR
Wstawka	INSR	Grubość	THKNS
L	LGE	Typ	TYP
Lewa	◀ LFT	Z	W/
Długość	LNTH	Bez	W/O
Średni — M	MED		

Ελληνικά

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ ΓΙΑ ΤΟ ΣΥΣΤΗΜΑ ΟΛΙΚΗΣ ΑΡΘΡΟΠΛΑΣΤΙΚΗΣ ΓΟΝΑΤΟΣ TRIATHLON TRITANIUM ΤΗΣ HOWMEDICA OSTEONICS

Περιγραφή

Τα συστήματα ολικής αρθροπλαστικής γόνατος της Howmedica Osteonics Corp. περιλαμβάνουν τη Βάση Πλάκας Triathlon Tritanium που έχει σχεδιαστεί για χρήση με τα μηριαία στελέχη Αρχικών συστημάτων ολικής αρθροπλαστικής γονάτου Triathlon, κνημιαία και επιγονατιδικά στελέχη για ολική αντικατάσταση της άρθρωσης γονάτου. Τα χαρακτηριστικά που είναι συγκεκριμένα για κάθε συσκευή περιγράφονται λεπτομερώς στην ετικέτα του προϊόντος. Η Βάση Πλάκας Triathlon Tritanium ενδείκνυται τόσο για εφαρμογές με τσιμέντο όσο και για εφαρμογές χωρίς τσιμέντο.

Μηριαία Στελέχη: Η Βάση Πλάκας Triathlon Tritanium είναι συμβατή με τα σχέδια χιαστής συγκράτησης Triathlon (CR), και χιαστής στέρησης (οπίσθια σταθεροποίηση – PS).

Κνημιαία Στελέχη: Η Βάση Πλάκας Triathlon Tritanium είναι συμβατή με τα σχέδια κνημιαίων ένθετων σε χιαστή συγκράτηση (CR), οπίσθιας σταθεροποίησης (PS), και κονδυλικής σταθεροποίησης (CS). Τα κνημαία ένθετα διαθέτονται σε εύρος πάχους και σε διάφορους βαθμούς συγκράτησης.

Σημείωση: Η Βάση Πλάκας Triathlon Tritanium έχει συσκευαστεί μαζί με Επίθεμα Προσκρουστήρα. Το Επίθεμα Προσκρουστήρα πρέπει να χρησιμοποιηθεί μόνο κατά τη διάρκεια του βήματος πρόσκρουσης στη κνημιαία βάση πλάκας και πρέπει να απορριφθεί αφότου ολοκληρωθεί η πρόσκρουση. Το Επίθεμα Προσκρουτήρα δεν ενδείκνυται για εμφύτευση.

Επιγονατιδικά Στελέχη: Τα στελέχη επιγονατιδικής επανόρθωσης διατίθενται σε σχέδια που είναι συμμετρικά και ασύμμετρα και εξ ολοκλήρου πλαστικά και σε σχέδια με μεταλλική πλάτη. Η χρήση επιγονατιδικών στελεχών είναι προαιρετική. Η Βάση Πλάκας Triathlon Tritanium είναι συμβατή με όλα τα επιγονατιδικά στελέχη.

Materials

• ASTM F-75 κράμα κοβαλτίου χρωμίου	Μηριαία στελέχη
• ASTM F-90 κράμα κοβαλτίου χρωμίου	Σύρμα ασφάλισης για κνημιαία ένθετα
• ASTM F-1537 κράμα κοβαλτίου χρωμίου	Μηριαίες σφήνες
• ASTM F-136 κράμα τιτανίου	Κνημιαία στελέχη
• ASTM F-67 CP Τιτάνιο	Κνημιαία στελέχη
• ASTM F-1185 φωσφορικό ασβέστιο	Μηριαία στελέχη, επιγονατιδικά στελέχη
• ASTM F-648 Πολυαιθυλένιο υπερυψηλού μοριακού βάρους	Κνημιαία ένθετα στήριξης, επιγονατιδικά στελέχη

Ενδείξεις

Γενικές ενδείξεις για ολική αρθροπλαστική γόνατος (ΟΑΓ):

- Επώδυνη νόσος των αρθρώσεων του γονάτου συνοδευόμενη από αναπηρία και προερχόμενη από: μη φλεγμονώδης εκφυλιστική αρθροπάθεια (συμπεριλαμβανομένης και της οστεοαρθρίτιδας, τραυματικής αρθρίτιδας, ή ανάγγειας νέκρωσης), ρευματοειδούς αρθρίτιδας ή μετατραυματικής αρθρίτιδας.
- Μετατραυματική απώλεια της διαμόρφωσης και λειτουργίας της άρθρωσης γονάτου.
- Ήπιου βαθμού παραμόρφωση βλασού, βραχίονα ή κάμψης στην οποία οι δομές συνδέσμου δύνανται να επαναφερθούν σε επαρκή λειτουργία και σταθερότητα.
- Επανόρθωση προηγούμενης αποτυχημένης αντικατάστασης γονάτου ή άλλης διαδικασίας.
- Θλάση του περιφερικού μηρού ή/ και της εγγύς κνήμης που δεν δύναται να σταθεροποιηθεί με τυπικές τεχνικές διαχείρισης θλάσης.

Η Βάση Πλάκας Triathlon Tritanium ενδείκνυται τόσο για χρήση με τσιμέντο όσο και για χρήση χωρίς τσιμέντο.

Συμπληρωματικές ενδείξεις για στελέχη με Οπίσθια Σταθεροποίηση (PS):

- Συνδεσμική αστάθεια χρήζουσα γεωμετρίες επιφάνειας στήριξης του εμφυτεύματος με αυξανόμενη συγκράτηση.
- Απών ή δυσλειτουργικό χιαστό σύνδεσμο.
- Σοβαρή πρόσθια και οπίσθια αστάθεια της άρθρωσης γονάτου.

Αντενδείξεις

- Κάθε ενεργή λοίμωξη ή υποψία λανθάνουσας λοίμωξης στην άρθρωση του γονάτου ή γύρω από αυτήν.
- Απομακρυσμένη εστία λοίμωξης που ενδέχεται να προκαλέσει αιματογενή εξάπλωση στην περιοχή εμφύτευσης.
- Κάθε διανοητική ή νευρομυϊκή δυσλειτουργία η οποία θα μπορούσε να δημιουργήσει απαράδεκτο κίνδυνο για αστάθεια της πρόθεσης, αποτυχία στερέωσης της πρόθεσης, ή επιπλοκές στη μετεγχειρητική αγωγή.
- Συρρίκνωση οστικής μάζας εξ αιτίας νόσου, λοίμωξης ή προηγούμενης εμφύτευσης λόγω της οποίας το οστό αδυνατεί να στηρίξει ή / και να στερεώσει την πρόθεση.
- Ανεπαρκής σκελετική ανάπτυξη.
- Σοβαρή αστάθεια της άρθρωσης γονάτου δευτερεύουσα στην απώλεια έμμεσης ακεραιότητας και λειτουργίας του συνδέσμου.
- Παχυσαρκία. Ένας υπέρβαρος ή παχύσαρκος ασθενής ενδέχεται να παράγει φορτία στην πρόθεση που μπορεί να οδηγήσουν σε αποτυχία της στερέωσης της συσκευής ή στην αποτυχία της ίδιας της συσκευής.

Προφυλάξεις

- Οι χειρουργοί πρέπει να συμβουλέψουν τους ασθενείς σχετικά με τα όρια της ανακατασκευής και την ανάγκη για προστασία του εμφυτεύματος από πλήρη στήριξη βάρους μέχρις ότου έχει επιτευχθεί επαρκής στερέωση και ίαση. Η υπερβολική δραστηριότητα και το τραύμα που επηρεάζουν την αντικατάσταση της άρθρωσης έχουν συνδεθεί με την αποτυχία της επανόρθωσης μέσω χαλάρωσης, θλάσης ή /και φθοράς των εμφυτευμάτων πρόθεσης. Η χαλάρωση των στελεχών μπορεί να έχει ως αποτέλεσμα αυξανόμενη παραγωγή των μορίων φθοράς, καθώς και βλάβη στο οστό, καθιστώντας δύσκολη την επιτυχή επέμβαση αναθεώρησης.
- Οι χειρουργοί θα πρέπει να προειδοποιήσουν τους ασθενείς να περιορίσουν τις δραστηριότητες και να προστατεύσουν την άρθρωση που αντικαθίσταται από υπερβολικές τάσεις και να τηρήσουν τις οδηγίες του ιατρού όσον αφορά την επακόλουθη φροντίδα και θεραπεία.
- Οι χειρουργοί πρέπει να προειδοποιούν τους ασθενείς σχετικά με τις πιθανές παρενέργειες, συμπεριλαμβανομένης και της περιορισμένης διάρκειας της συσκευής και την ανάγκη για την μετεγχειρητική προστασία του εμφυτεύματος. Ο χειρουργός πρέπει να προειδοποιεί τους ασθενείς ότι η συσκευή δεν αντικαθιστά την ευλυγισία, ισχύ, αξιοπιστία ή ανθεκτικότητα μιας φυσιολογικής υγιής άρθρωσης και ότι το εμφύτευμα ενδέχεται να σπάσει ή να υποστεί βλάβη ώς αποτέλεσμα επίπονης δραστηριότητας ή τραύματος.
- Η κατάλληλη επιλογή, τοποθέτηση και στερέωση των στελεχών ολικής αρθροπλαστικής γόνατος είναι κρίσιμοι παράγοντες που επηρεάζουν τη διάρκεια ζωής του εμφυτεύματος. Όπως και στην περίπτωση όλων των πρόσθετων εμφυτευμάτων, η αντοχή αυτών των στελεχών επηρεάζεται από διάφορους βιολογικούς, βιο-μηχανικούς και άλλους εξωτερικούς παράγοντες, οι οποίοι επηρεάζουν τη διάρκεια ζωής τους. Για το λόγο αυτό, απαιτείται να ακολουθηθούν πιστά οι ενδείξεις, αντενδείξεις, προφυλάξεις και προειδοποιήσεις αυτού του προϊόντος προκειμένου να επιτευχθεί η μέγιστη διάρκεια ζωής του.

Χρήση και εμφύτευση

- Χρησιμοποιήστε τα συνιστώμενα στελέχη για τον καθορισμό μεγέθους, τη μείωση δοκιμής και την αξιολόγηση εύρους κίνησης, διατηρώντας έτσι την ακεραιότητα των πραγματικών εμφυτευμάτων και την αποστειρωμένη συσκευασία τους.

- Διατίθενται ακτινογραφικές πλάκες για να βοηθήσουν στις προεγχειρητικές προβλέψεις για το μέγεθος και το στιλ του στελέχους.
- Θα πρέπει να δοθεί προσοχή για να αφαιρεθούν τα οστικά κομματάκια, τεμάχια οστικού τσιμέντου και τα μεταλλικά υπολείμματα από την περιοχή εμφύτευσης προς μείωση της επιταχυνόμενης φθοράς της αρθρωτής πρόθεσης του εμφυτεύματος που προκύπτει από τα υπολείμματα που παράγονται.
- Τα Χειρουργικά Πρωτόκολλα της Howmedica Osteonics Corp. Παρέχουν συμπληρωματικές πληροφορίες διαδικασίας.
- Συμβουλευθείτε την ετικέτα του προϊόντος σχετικά με τη συγκεκριμένη συμβατότητα του προϊόντος. Γενικά, ισχύουν τα ακόλουθα:
  - Χρησιμοποιήστε μηριαία PS μόνο με Κνημιαία Στηρίγματα PS
  - Χρησιμοποιήστε μηριαία CR μόνο με Κνημιαία Στηρίγματα CR
  - Χρησιμοποιήστε είτε μηριαία PS ή CR με Κνημιαία Στηρίγματα CS

Πληροφορίες για τους ασθενείς

- Ο χειρουργός θα πρέπει να δώσει συμβουλές στον ασθενή για τους περιορισμούς της επανόρθωσης και την ανάγκη προστασίας από πλήρη φόρτιση βάρους μέχρις ότου επέλθει επαρκής σταθεροποίηση και ίαση. Η υπερβολική δραστηριότητα και το τραύμα που επηρεάζουν την αντικατάσταση άρθρωσης αποτελούν μέρος της αποτυχίας της επανόρθωσης λόγω χαλάρωσης, θραύσης ή / και φθοράς των προσθετικών εμφυτευμάτων. Η χαλάρωση των στοιχείων μπορεί να έχει ως αποτέλεσμα αυξημένη παραγωγή σωματιδίων που προκαλούν φθορά, καθώς και βλάβη στο οστό, καθιστώντας πιο δύσκολη την επιτυχή επέμβαση αναθεώρησης.
- Ο χειρουργός θα πρέπει να συμβουλεύσει τον ασθενή να περιορίσει τις δραστηριότητες και να προστατεύσει την άρθρωση από παράλογη τάση, και να τηρήσει τις οδηγίες του ιατρού σχετικά με τη θεραπεία παρακολούθησης.
- Ο χειρουργός θα πρέπει να προειδοποιήσει τον ασθενή σχετικά με τους κινδύνους της εγχείρησης, και τις πιθανές παρενέργειες. Ο χειρουργός θα πρέπει να προειδοποιήσει τον ασθενή ότι η συσκευή δεν αντικαθιστά μια φυσιολογική υγιή άρθρωση, ότι το εμφύτευμα μπορεί να σπάσει ή να καταστραφεί ως αποτέλεσμα υπερβολικής δραστηριότητας ή τραύματος, και ότι η συσκευή έχει ορισμένη διάρκεια ζωής και μπορεί να χρειαστεί να αντικατασταθεί στο μέλλον.
- Στην καθημερινή ζωή μπορεί να εμφανιστεί παροδική ύπαρξη βακτηρίων στο αίμα. Οδοντιατρικές επεμβάσεις, ενδοσκοπικές εξετάσεις και άλλες δευτερεύουσας σημασίας χειρουργικές επεμβάσεις έχουν επίσης συνδεθεί με την παροδική ύπαρξη βακτηρίων στο αίμα. Για να αποφεύγονται μολύνσεις στα σημεία εμφύτευσης, ίσως πρέπει να λαμβάνεται αντιβιοτική προφύλαξη πριν και μετά από επεμβάσεις αυτού του είδους.

Προειδοποιήσεις

- Απορρίψτε όλα τα κατεστραμμένα εμφυτεύματα ή τα εμφυτεύματα που έχουν τεθεί υπό άσχημη μεταχείριση.
- Μην επαναχρησιμοποιείτε ποτέ ένα εμφύτευμα, ακόμη και αν φαίνεται ακέραιο.
- Μην εμφυτεύετε το Επίθεμα Πρόσκρουσης. Το Επίθεμα Πρόσκρουσης πρέπει να χρησιμοποιηθεί μόνο στο βήμα κνημιαίας πρόσκρουσης. Αφαιρέστε το και πετάξτε το αμέσως μετά τη διαδικασία εμφύτευσης.
- Μην αφήνετε τις γυαλισμένες περιοχές στήριξης να έρθουν σε επαφή με σκληρές ή διαβρωτικές επιφάνειες.
- Οι περιοχές στήριξης πρέπει να είναι πάντοτε καθαρές και χωρίς υπολείμματα πριν από τη συναρμολόγηση.
- Η χάραξη των υψομετρικών καμπύλων ή το λύγισμα ενός εμφυτεύματος ενδέχεται να μειώσει την ισχύ κόπωσής του και να προκαλέσει δυσλειτουργία υπό φορτίο.
- Το μεταλλικό σύρμα συγκράτησης στο ένθετο δεν πρέπει να τεθεί υπό χειρισμό ή να αφαιρεθεί, διότι είναι κρίσιμο για την ασφάλεια της συναρμολόγησης. Πετάξτε κάθε κνημιαίο ένθετο στήριξης εάν το μεταλλικό σύρμα συγκράτησης φαίνεται κατεστραμμένο ή έχει υποστεί κακή μεταχείριση.

Η παραποίηση αυτής της συναρμολόγησης μπορεί να έχει ως αποτέλεσμα την ακατάλληλη λειτουργία του μηχανισμού συγκράτησης.

- Θα πρέπει να δοθεί προσοχή για να μην κοπούν τα χειρουργικά γάντια όταν χειρίζεστε οποιαδήποτε ορθοπεδική συσκευή με αιχμηρά άκρα.
- Εκτός και όπου σημειώνεται, η Howmedica Osteonics Corp. συνιστά θερμά να μην χρησιμοποιούνται στελέχη ολικής αρθροπλαστικής γόνατος από άλλον κατασκευαστή με οποιαδήποτε από τα στελέχη ολικής αρθροπλαστικής γόνατος της Howmedica Osteonics. Οποιαδήποτε παρόμοια χρήση θα αναιρέσει την ευθύνη της Howmedica Osteonics Corp. για την απόδοση του εμφυτεύματος που προέκυψε από συναρμολόγηση με εξαρτήματα διαφορετικών κατασκευαστών.
- Η Howmedica Osteonics Corp. αντιτίθεται στη χρήση βίδας οστών άλλου κατασκευαστή με οποιοδήποτε στέλεχος ολικής αρθροπλαστικής γόνατος της Howmedica Osteonics, εξαιτίας διαφοροποιήσεων που πιθανόν να υπάρχουν στην κεφαλή και στον τρόπο διαμόρφωσης για την τοποθέτηση της βίδας.
- Η εκούσια αφαίρεση στελέχους ολικής αρθροπλαστικής γόνατος μπορεί να επιτευχθεί με την προσεκτική χρήση γλυφάνων κοπής, λεπτών και στενών οστεοτόμων και προσεκτικής ισχύος εξαγωγής.
- Η εκούσια αφαίρεση πλαστικού κνημιαίου ένθετου μετά τη συναρμολόγησή του στη μεταλλική βάση πλάκας έχει ως αποτέλεσμα την καταστροφή του πλαστικού ένθετου. Θα πρέπει να δοθεί προσοχή να μην κόψετε την επιφάνεια της κνημιαίας βάσης πλάκας κατά τη διάρκεια αφαίρεσης του ένθετου.
- Επιστρέψτε όλες τις συσκευασίες που φέρουν ελαττώματα στο αποστειρωμένο φράγμα τους στον προμηθευτή. **Μην επαναποστειρώνετε.**

Ανεπιθύμητες παρενέργειες

- Αν και η διάρκεια ζωής των στελεχών ολικής αρθροπλαστικής γόνατος είναι δύσκολο να εκτιμηθεί, γεγονός είναι ότι είναι περιορισμένη. Τα στελέχη αυτά είναι κατασκευασμένα από ξένα προς τον ανθρώπινο οργανισμό υλικά, τα οποία εμφυτεύονται στο ανθρώπινο σώμα για την πιθανή αποκατάσταση κινητικότητας του ατόμου ή την ελάττωση του πόνου. Παρόλα αυτά εξαιτίας ενός μεγάλου αριθμού βιολογικών, μηχανικών και φυσικοχημικών παραγόντων οι οποίοι επηρεάζουν τη σωστή λειτουργία αυτών και οι οποίοι δεν μπορούν να εκτιμηθούν εν ζωή (*in vivo*), δεν πρέπει κάποιος να αναμένει ότι τα στελέχη αυτά θα αντέξουν επ' αόριστο το βαθμό σωματικής δραστηριότητας και τα διάφορα φορτία τα οποία αντέχει ένα φυσιολογικό υγιές οστό. Οι χειρουργοί θα πρέπει να συμβουλεύουν τους ασθενείς να μην έχουν υπερβολικές προσδοκίες σχετικά με τη διάρκεια ζωής της συσκευής.
- Μπορεί να επέλθει εξάρθρωση της μηριαίας, κνημιαίας, ή επιγονατιδικής πρόθεσης εξαιτίας ανάρμοστης σωματικής δραστηριότητας του ασθενούς, τραύματος ή κάποιου βιομηχανικού παράγοντα.
- Είναι πιθανόν να συμβεί χαλάρωση των στελεχών ολικής αρθροπλαστικής γόνατος. Η πρώιμη μηχανική χαλάρωση μπορεί να είναι το αποτέλεσμα ανεπαρκούς αρχικής στήριξης, λανθάνουσας λοίμωξης, πρόωρης έκθεσης της πρόθεσης σε φορτία, λανθασμένης ευθυγράμμισης του στελέχους ή τραύματος. Όψιμη χαλάρωση της πρόθεσης μπορεί να προκληθεί από τραυματισμό, λοίμωξη, βιολογικές επιπλοκές συμπεριλαμβανομένης της οστεόλυσης, ή από μηχανικά προβλήματα, με αποτέλεσμα ενδεχόμενη διάβρωση του οστού ή / και πόνο.
- Έχει αναφερθεί θραύση των στελεχών ολικής αθροπλαστικής γόνατος από κόπωση, που περιλαμβάνουν τα κνημιαία, μηριαία και επιγονατιδικά στελέχη, σε μικρό ποσοστό ασθενών. Η θραύση στελεχών γονάτου ενδέχεται να προκύψει εξαιτίας ανεπαρκούς υποστήριξης του στελέχους από το υποκείμενο οστό ή εξαιτίας άσχημης στερέωσης του στελέχους.
- Είναι πιθανόν να επέλθει περιφερική νευροπάθεια, βλάβη των νεύρων, κυκλοφορικό πρόβλημα, και έκτοπη οστεοποίηση.
- Ενδέχεται να σχετίζονται σοβαρές επιπλοκές με κάθε επέμβαση ολικής αρθροπλαστικής. Οι επιπλοκές αυτές περιλαμβάνουν, μεταξύ άλλων: διαταραχές του ουροποιογεννητικού συστήματος, γαστρεντερικές διαταραχές, αγγειακές διαταραχές συμπεριλαμβανομένης της θρόμβωσης, βρογχοπνευμονικές διαταραχές συμπεριλαμβανομένης της εμβολής, έμφραγμα του μυοκαρδίου ή και θάνατο.
- Έχει αναφερθεί φθορά των στελεχών πολυαιθυλενίου και οι αναφορές στη βιβλιογραφία συνδέουν αυτό το συμβάν με την επαναρρόφηση οστού, τη χαλάρωση και τη λοίμωξη.

- Έχουν αναφερθεί αντιδράσεις ευαισθησίας στα μέταλλα μετά από επέμβαση αρθροπλαστικής.
- Η εμφάνιση ανεπιθύμητων ενεργειών πιθανόν να απαιτεί πρόσθετη εγχείρηση, διόρθωση, αρθρόδεση της σχετικής άρθρωσης ή /και ακρωτηριασμό του μέλους.
- Έχει συσχετιστεί η ανισορροπία μαλακού ιστού ή / και χαλαρότητα με τη λανθασμένη ευθυγράμμιση στελέχους, πράγμα το οποίο ενδέχεται να έχει ως αποτέλεσμα την πρώιμη φθορά ή / και την αποτυχία του εμφυτεύματος.
- Όπως είναι φυσικό με όλες τις εμφυτευμένες συσκευές, μπορεί να παρατηρηθεί ασυμπτωματικά προοδευτική απορρόφηση του οστού (οστεόλυση) τοπικά γύρω από τα εξαρτήματα της πρόθεσης ως επακόλουθο της αντίδρασης προς το ξένο για τον οργανισμό σώμα με το κοκκίωμα τσιμέντου, μετάλλου, το υπερυψηλού μοριακού βάρους πολυαιθυλένιο (ultra-high molecular weight polyethylene [UHMWPE]) ή και το κεραμικό υλικό. Δημιουργείται κοκκίωμα εξαιτίας της αλληλεπίδρασης μεταξύ των στελεχών, καθώς και μεταξύ των στελεχών και οστού, κυρίως εξαιτίας μηχανισμών φθοράς, σύμφυσης, εκδοράς και κόπωσης. Επιπλέον, μπορεί να δημιουργηθεί επίσης κοκκίωμα εξαιτίας της επίδρασης κάποιου τρίτου σώματος. Η οστεόλυση μπορεί να οδηγήσει σε μελλοντικές επιπλοκές συμπεριλαμβανομένης της χαλάρωσης, γεγονός που καθιστά αναγκαία την αφαίρεση και αντικατάσταση της πρόθεσης.
- Είναι γνωστό ότι μερικά πολύ μικρά μόρια από εξαρτήματα μετάλλου και πολυαιθυλενίου μπορεί να πέσουν από τα εξαρτήματα κατά τη διάρκεια συνήθους χρήσης και με την πάροδο του χρόνου. Αν και τα περισσότερα από αυτά τα υπολείμματα παραμένουν εντός του σχετικού συνδέσμου (π.χ. περιέχονται στον αρθροσίελο) ή είναι παγιδευμένα από παρακείμενο ιστό, τα μικροσκοπικά μόρια δύνανται να μετακινηθούν διαμέσου του σώματος. Προς το παρόν, υπάρχουν ερωτήσεις που δεν μπορούμε να απαντήσουμε σχετικά με τα υπολείμματα και τα μικροσκοπικά μόρια που δημιουργούνται από αυτά τα εξαρτήματα. Έχει αποδειχθεί ότι τα μικροσκοπικά μόρια υπολειμμάτων δύνανται να διασπαρθούν (μετακινηθούν) διαμέσου του σώματος και σε ορισμένες περιπτώσεις έχει αναφερθεί ότι συσσωρεύονται στους λεμφαδένες και σε άλλα μέρη του σώματος. Αν και μέχρι τώρα δεν έχουν αναφερθεί σημαντικές ιατρικές επιπλοκές ως αποτέλεσμα αυτών των μορίων, η μετακίνησή τους ή / και η συσσώρευσή τους στο σώμα έχει αναφερθεί σε βιβλιογραφία. Λόγω του ανεπαρκούς χρόνου κατά τη διάρκεια του οποίου παρακολουθούνται οι ασθενείς που έχουν αυτές τις συσκευές και λόγω του ότι οι συσκευές αυτές χρησιμοποιούνται προς το παρόν σε νεότερης ηλικίας ασθενείς και παραμένουν εντός του σώματος για αυξανόμενες περιόδους χρόνου, πρέπει να δηλωθεί ότι οι μακροχρόνιες επιδράσεις από αυτά τα μόρια, εάν υπάρχουν, είναι άγνωστες. Υπάρχει η θεωρία ότι οι μακροχρόνιες επιδράσεις περιλαμβάνουν:
  - **Καρκίνο:** Προς το παρόν δεν υπάρχουν επιστημονικές αποδείξεις που σχετίζουν τα μεταλλικά υπολείμματα ή τα υπολείμματα πολυαιθυλενίου με καρκίνο. Ωστόσο, δεν δύναται να απαλειφθεί η πιθανότητα.
  - **Λεμφαδενοπάθεια και συσσώρευση σε άλλους ιστούς ή σε άλλα όργανα:** Υπάρχουν μερικές αναφορές συσσώρευσης υπολειμμάτων φθοράς σε λεμφαδένες (εγγύς και περιφερικά). Αν και δεν έχουν αναφερθεί ιατρικές επιπλοκές ή ασθένειες ως αποτέλεσμα αυτών των συσσωρεύσεων, η ύπαρξή τους πρέπει να αναγνωριστεί για την διευκόλυνση διάγνωσης και την αποφυγή σύγχυσης με υποψιαζόμενες κακώσεις, καρκινογόνες ή μη.
  - **Συστηματική ασθένεια:** Υπάρχουν ορισμένες θεωρίες που υποστηρίζουν ότι μπορεί να υπάρχει συσχέτιση μεταξύ της μετακίνησης των υπολειμμάτων και των έως τώρα απροσδιόριστων συστηματικών επιδράσεων. Είναι πιθανόν να αποδειχθεί κάποια μακροχρόνια επίδραση στο μέλλον, αλλά λόγω του ότι υπάρχουν πολύ ελάχιστα επιστημονικά δεδομένα που υποδεικνύουν συσχέτιση μεταξύ της μετακίνησης των υπολειμμάτων και κάποιας συστηματικής ασθένειας, θεωρείται ότι τα οφέλη από αυτές τις συσκευές υπερβαίνουν προφανώς τους πιθανούς κινδύνους για οποιαδήποτε θεωρητική μακροχρόνια επίδραση.

Αλληλεπίδραση με Απεικόνιση Μαγνητικής Τομογραφίας

Το Σύστημα Αρθροπλαστικής Γονάτου Triathlon δεν έχει αξιολογηθεί για ασφάλεια και συμβατότητα σε περιβάλλον μαγνητικής τομογραφίας. Το Σύστημα Αρθροπλαστικής Γονάτου Triathlon δεν έχει τεθεί υπό δοκιμασία για θέρμανση ή μετατόπιση σε περιβάλλον μαγνητικής τομογραφίας.

Αποστείρωση

- Αυτό το εξάρτημα ολικής αρθροπλαστικής γονάτου έχει αποστειρωθεί με ακτινοβολία γάμμα ή πλάσμα αερίου υπεροξειδίου του υδρογόνου. Αναφερθείτε στην ετικέτα της συσκευασίας σχετικά με τη μέθοδο αποστείρωσης.
- Θα πρέπει να επιθεωρείτε τη συσκευασία όλων των αποστειρωμένων προϊόντων για τυχόν ελαττώματα στο αποστειρωμένο φράγμα τους προτού τα ανοίξετε. Εάν υπάρχει κάποιο ελάττωμα, το προϊόν πρέπει να θεωρηθεί μη αποστειρωμένο. Διατίθενται ειδικές προθέσεις δοκιμής για να μην χρειάζεται να ανοίξετε οποιοδήποτε μέρος της αποστειρωμένης συσκευασίας πριν από τη χρήση του εξαρτήματος.
- Θα πρέπει να δωθεί προσοχή προς αποφυγή μόλυνσης του εξαρτήματος. Σε περίπτωση που μολυνθεί το προϊόν, θα πρέπει να το απορρίψετε.
- Εάν η συσκευασία έχει ανοιχτεί, αλλά το προϊόν δεν έχει χρησιμοποιηθεί, το εξάρτημα δεν πρέπει να επαναποστειρωθεί και πρέπει να απορριφθεί ή να επιστραφεί στον προμηθευτή.
- Η συσκευή δεν πρέπει να χρησιμοποιηθεί αφότου παρέλθει η ημερομηνία λήξης που αναγράφεται στην ετικέτα της συσκευασίας, διότι το προϊόν δεν έχει αξιολογηθεί για χρήση μετά από αυτήν την ημερομηνία.
- Συσκευές μίας χρήσης δεν μπορούν να εκφυτευτούν και να εμφυτευτούν εκ νέου κατόπιν καθώς οι φυσικές δυνάμεις που ασκούνται από αυτές τις ενέργειες ενδέχεται να διακυβεύσουν τη φυσική ακεραιότητα, τις διαστάσεις ή/ και το φινίρισμα της επιφάνειας των συσκευών. Επίσης, δεν δύναται να διασφαλιστεί η στειρότητα των συσκευών που έχουν χρησιμοποιηθεί εκ νέου καθώς δεν έχουν επαληθευτεί οι διαδικασίες καθαρισμού και επαναποστείρωσης.

ΠΡΟΣΟΧΗ: **ΤΟ ΟΜΟΣΠΟΝΔΙΑΚΟ ΔΙΚΑΙΟ (Η.Π.Α.) ΠΕΡΙΟΡΙΖΕΙ ΤΗΝ ΠΩΛΗΣΗ ΤΗΣ ΣΥΣΚΕΥΗΣ ΣΕ ΙΑΤΡΟ Ή ΚΑΤΟΠΙΝ ΕΝΤΟΛΗΣ ΙΑΤΡΟΥ.**

ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Τα εξαρτήματα που φέρουν την επισήμανση «Μόνο για χρήση με τσιμέντο» πρέπει να εμφυτεύονται μόνο με οστικό τσιμέντο.

Ανατρέξτε στην ετικέτα του προϊόντος για την υπόσταση της σήμανσης CE και τον νόμιμο κατασκευαστή. Η σήμανση CE είναι έγκυρη μόνο αν αναγράφεται επίσης στην ετικέτα του προϊόντος.

Ο ακόλουθος πίνακας περιλαμβάνει έναν κατάλογο των συντμήσεων που χρησιμοποιούνται στην ετικετοποίηση των προϊόντων της Howmedica Osteonics Corp. :

Όρος	Σύντμηση	Όρος	Σύντμηση
Κωδικός Άλφα	ALPH CDE	Λαιμός	NK
Γωνία	ANG	Απόσταση	OFFST
Βαθμός	DEG or °	Εξωτερική Διάμετρος	OD
Διάμετρος	DIA	Δεξιός	RT ▶
Εξαιρετικά βαθύς	XDP	Οπές βιδών	SCR HLS
Εξαιρετικά μεγάλος	XLGE	Πλευρά	SDE
Εξαιρετικά μικρός	XSM	Μέγεθος	SZE
Κεφαλή	HD	Μικρός	SM
Ύψος	HT	Συνήθης	STD
Εσωτερική Διάμετρος	ID	Κωνικός	TPR
Ένθεμα	INSR	Πάχος	THKNS
Μεγάλος	LGE	Τύπος	TYP
Αριστερός	◀ LFT	Με	W/
Μήκος	LNTH	Χωρίς	W/O
Μέσο	MED		

简体中文 Chinese

HOWMEDICA OSTEONICS 的 TRIATHLON TRITANIUM 全膝关节使用说明

说明

Howmedica Osteonics Corp.司的全膝关节系统包括 Triathlon Tritanium 底板，用于与 Triathlon 主要膝关节系统股骨组件、胫骨内衬和髌骨组件一起使用以进行膝关节的整体重建置换。产品标签上有关于各组件具体特征的详细说明。Triathlon Tritanium 底板适用于无骨水泥和骨水泥的应用。

股骨组件：Triathlon Tritanium 底板与 Triathlon 十字韧带固位（CR）和十字韧带切除（后稳式 - PS）设计兼容。

胫骨组件：Triathlon Tritanium 底板与十字韧带固位（CR）、后稳式（PS）以及髁固位（CS）设计中的 Triathlon 胫骨内衬兼容。胫骨内衬提供一系列厚度和各种拘束度。

注：Triathlon Tritanium 底板与锤入器垫包装在一起。锤入器垫将用于胫骨底板嵌入步骤期间，一旦嵌入完成，即予以丢弃。锤入器垫不适合用于植入。

髌骨组件：全塑对称与不对称以及金属衬背设计均提供髌骨再涂层组件。髌骨组件的使用是可选的。Triathlon Tritanium 底板与所有的 Triathlon 髌骨组件兼容。

材料

• ASTM F-75 钴铬合金	股骨组件
• ASTM F-90 钴铬合金	胫骨内衬的锁定丝
• ASTM F-1537 钴铬合金	股骨骨钉
• ASTM F-136 钛合金	胫骨组件
• ASTM F-67 CP 钛	胫骨组件
• ASTM F-1185 磷酸钙	股骨组件、髌骨组件
• ASTM F-648 超高分子量聚乙烯	胫骨承托内衬、髌骨组件

适应症

全膝关节置换术（TKR）一般适应症：

- 由于以下原因引起的膝盖疼痛、致残性关节疾病：非炎症性退行性关节疾病（包括骨关节炎、创伤性关节或无血管性坏死）、风湿性关节炎或创伤后关节炎。
- 膝关节构造和功能创伤后丧失。
- 中度内翻足、外翻足或弯曲畸形，患者的韧带组织可充分恢复功能和稳定性。
- 修正以前不成功的膝盖置换或其他手术。
- 无法用标准骨折处理技法固位的远端股骨和/或近端胫骨骨折。

Triathlon Tritanium 底板同时适用于无骨水泥和骨水泥固定的用途。

后端稳定型（PS）组件的其他适应症：

- 由于韧带不稳定，而要求增加约束强度的植入体承托表面几何结构。
- 缺少或失去功能的后十字韧带。
- 膝关节前后侧严重不稳。

禁忌症

- 膝关节内或周围发生任何活动性感染，或怀疑有潜伏性感染。
- 可能导致血源性传播到植入部位的远处感染灶。
- 任何可导致假体不稳定、假体固定失灵或者术后护理并发症等难以承受的风险之精神疾病或神经肌肉疾病。
- 骨存量由于疾病、感染或先前植入而受损，无法对假体提供充分的支持和/或固定作用。
- 骨骼发育不全。
- 侧面韧带残缺和功能不全的继发膝关节严重不稳。
- 肥胖症。超重或肥胖患者可能对假体形成负荷，从而导致装置固定失灵或装置本身失灵。

预防措施

- 外科医生应当告知患者关节重建的局限性，还要避免植入物承受身体全重，直到充分固定和愈合。过量活动和外伤可能因假体植入物的松动、破裂和/或磨损导致重建失败，从而影响关节置换物的功能。植入物组件的松动可能增加磨损颗粒的产生，对骨骼造成伤害，使翻修手术较难成功。
- 外科医生应告诫患者要限制活动，避免置换关节承受过度压力，并且要遵循医生的指示进行随访护理和治疗。
- 外科医生应警告患者潜在的不良作用，包括装置的有限使用寿命以及手术后对植入体的保护。外科医生应当警告患者，植入装置没有正常健康关节的灵活性、强度、可靠性或持久性，并且可能会由于剧烈活动或外伤而破裂或损坏。
- 全膝组件的正确选择、安置和固定，是影响假体使用寿命的关键因素。这些组件同所有假体植入物一样，受到各种生物学、生物力学和其他外在因素的影响，限制其使用生命。因此，必须严格遵守关于本产品适应症、禁忌症、预防措施和警示事项的规定，才能充分延长产品的使用寿命。

使用和植入

- 使用所推荐的试验组件来决定假体大小、试验复位和评估活动度，从而保持实际植入体的完整性和无菌包装状态。
- 备有放射摄影模板，可用于协助在手术前预测组件尺寸和形态。
- 清除植入体部位的骨屑、骨水泥碎片和金属碎片时应小心，以降低因植入体关节表面加速磨损而诱发碎片的风险。
- 《Howmedica Osteonics Corp.司外科手术规程》中提供了手术操作补充信息。
- 有关具体产品的兼容性，请查阅产品标签。通常适用下列情况：
  - 仅与 PS 胫骨承托一起使用 PS 股骨
  - 仅与 CR 胫骨承托一起使用 CR 股骨
  - 与 CS 胫骨承托一起使用 PS 或 CR 股骨

患者须知

- 外科医生必须告知患者关节重建的局限性，还要避免植入物承受身体全重，直到充分固定和愈合。过量活动和外伤可能因假体植入物的松动、破裂和/或磨损导致重建失败，

从而影响关节置换物的功能。植入物组件的松动可能增加磨损颗粒的产生，对骨骼造成伤害，使翻修手术较难成功。

- 外科医生应当警告患者要限制活动，避免置换关节承受过度压力 ，并且要遵循医生的指示进行随访护理和治疗。
- 外科医生应当警告患者手术的危险及可能发生的不良反应。外科医生应当警告患者植入装置不是正常健康关节的复制品，它可能会由于剧烈活动或外伤而破裂或损坏，并且其使用寿命有限，未来可能需要更换。
- 患者在日常生活中可能会患短暂菌血症。牙齿操作、内窥镜检查和其他小外科手术也与短暂菌血症有关。为防止植入物部位发生感染，可在植入术前后采用抗生素预防。

警示事项

- 丢弃所有已损坏或操作不当的植入体。
- 切勿重新使用植入体，即使植入体看似完好。
- 请勿植入锤入器垫。锤入器垫仅用于胫骨底板嵌入步骤期间。嵌入程序后立即移除并丢弃。
- 切勿使抛光的承托表面接触坚硬或摩擦性表面。
- 承托区域在组装前必须始终保持干净，而且无任何碎屑。
- 假体外形改变或弯曲可能降低假体疲劳强度，并使之在负荷下失灵。
- 不应触动或取下内衬上的金属固位丝，这一固位丝对整个装配件的牢固性极为重要。如果金属固位丝看似损坏或被不当触动过，将胫骨承托内衬丢弃。随意改动本装配件可能导致固定机制功能失常。
- 操作任何边缘尖利的矫形外科器械时均应小心，切勿割破外科手术手套。
- 除非另有说明，否则 Howmedica Osteonics Corp. 司强烈建议不要将其他制造商生产的全膝组件与任何 Howmedica Osteonics 全膝组件一起使用。Howmedica Osteonics Corp. 司对任何上述混合组件植入体的功效概不承担责任。
- 由于螺钉和螺孔的配置有差异，Howmedica Osteonics Corp. 司强烈建议不要将其他制造商生产的骨螺钉与任何 Howmedica Osteonics 全膝组件一起使用。
- 如蓄意取出全膝组件，可使用骨钻和薄而窄的骨凿，并小心取出力道。
- 如在塑料胫骨内衬已装入金属底板后再蓄意取出，会毁坏塑料内衬。取出内衬时应小心操作，以免在胫骨底板表面留下划痕或刻痕。
- 用无菌包装材料包好所有带缺陷的产品，并退回给供应商。**不可重新作灭菌处理。**

不良反应

- 全膝置换组件的预期使用寿命很难估计，但肯定是有限度的。这些组件是用外源材料制造的，将其置入患者体内，以期恢复患者的活动能力或减少疼痛。但是，由于这些组件受到诸多生物学、力学和物理化学因素的影响，而对这些影响又无法作体内评定，因此不能期望这些组件能无限地承受正常健康骨骼所能承受的活动程度和负荷。外科医生应告知患者勿对装置寿命有不切实际的期待。
- 患者活动不当、外伤或其他生物力学原因都会引起股骨、胫骨或髌骨假体脱位。
- 可能会发生全膝组件松动的情况。组件的早期机械性松动可能是由于初始固定不当、

潜伏性感染、假体负荷过早、组件排列不齐或外伤而引起。可能会引起假体晚期松动的原因包括外伤、感染以及包括骨质溶解在内的生物学并发症或力学问题，并有可能导致后续的骨糜烂和/或疼痛。

- 曾发生过全膝组件，包括胫骨、股骨和髌骨组件的疲劳性破裂情况，但发生机率很小。由于底层骨对组件的支撑不够或者组件固定不佳，有可能导至膝盖组件破裂。
- 可能会发生外周神经疾病、神经损伤、循环受损和异位性骨化形成。
- 任何全关节置换手术都有可能引起严重的并发症。这些并发症包括但不限于：生殖泌尿疾病；胃肠疾病；血栓等血管疾病；栓塞等支气管肺疾病；心肌梗死或死亡。
- 曾发生过聚乙烯组件磨损的情况，并有文献指出其磨损与骨吸收、松动和感染有关。
- 曾有关节置换手术后发生金属过敏反应的报道。
- 如果发生不良作用，可能需要对相应关节重新做手术或进行翻修术、关节固定术和/或截肢。
- 软组织失衡和/或松弛一直与组件排列不齐有关，可能导致植入体的早期磨损和/或失败。
- 使用任何植入装置都有可能对骨水泥、金属、超高分子量聚乙烯（UHMWPE）和/或陶瓷的微粒物质发生异体反应，并因此在假体组件边缘出现无症状、局部渐进性骨吸收（骨质溶解）。这些微粒是在组件之间以及组件与骨骼之间的相互作用过程中产生的，主要是通过粘附、磨损和疲劳的耗损机制造成。其次，也可能由于第三介质磨损而产生。骨质溶解会导致未来的并发症，包括松动，而必须取出并置换假体组件。
- 一般认为，在正常使用期间或长期使用后，组件的金属和聚乙烯碎屑可能脱落一些极小的颗粒。虽然大部分碎屑会留在相关的关节中（即包含在滑膜中）或被周围伤痕组织捕获，但是微小颗粒也可能从关节外向身体其他部位移动或游移。当前，对于可能从这些组件产生的碎屑和微小颗粒还有悬而未决的疑问。已经证明，微小颗粒也可能向整个身体扩散（转移），偶尔有颗粒积累于淋巴结或身体其他部位的报道。虽然迄今为止没有因这些颗粒而造成严重医疗并发症的报道，但是文献中有关于这些颗粒在身体内游移和/或积累的记载。由于对这些装置植入患者的随访时间不够充分，加上这些装置目前正被用于较年轻的患者，并因此在体内存留更长的时间，应该说，如果这些颗粒会造成什么长期影响的话，这些后果是什么现在尚不清楚。从理论上分析，这些长期影响将包括：
  - **癌症：**目前尚无任何科学证据显示金属或聚乙烯碎屑与癌症有关。但不能排除这种可能性。
  - **淋巴结病以及在其他组织/器官中的积累：**曾有几例关于脱落颗粒积累于淋巴结（近端和远端淋巴结）的报道。虽然尚无因这些颗粒积累而导致并发症的报道，但应该了解这些颗粒的存在，以辅助病情诊断，避免与癌症或其他可疑病变发生混淆。
  - **全身性疾病：**有些推测认为，脱落颗粒的游移有可能与尚未明确的全身性影响有关。也许将来某个时候某些长期影响可能可以得到证实，但是由于目前能够推测这些颗粒游移与全身性疾病有关的科学数据极少，所以目前可以相信，使用这些装置的获益明显大于任何理论上的长期影响的潜在危险性。

与磁共振成像的交互作用

Triathlon 膝关节系统尚未经过磁共振环境下的安全性和兼容性评估。Triathlon 膝关节系统尚未经过磁共振环境下加热或游移的测试。

灭菌

- 本全膝组件已用伽马射线或过氧化氢气体等离子灭菌处理。灭菌方法请见包装标签。
- 在打开所有无菌产品包装之前，均应先检查无菌包装是否有缺陷。如果发现有缺陷，必须将这些产品视为非无菌产品。备有试验用假体模型，以免在使用组件之前打开无菌产品的任何包装部份。
- 应小心谨慎，防止假体组件受污染。如果产品受到污染，必须将其丢弃。
- 如果产品被打开但未使用，绝对不要将假体组件重新消毒，而应将其丢弃或退回给供应商。
- 装置不应在标签上显示的到期日之后使用，因为包装尚未经过超过该日期以后的验证。
- 一次性使用的装置不能取出之后再度植入，因为这些行动所施加的物理力量可能会破坏装置的物理完整性、大小和/或表面处理。由于清洁和重新灭菌程序尚未经过验证，因此也无法确保重新使用的装置的无菌性。

注意： **联邦法律（美国）规定，此装置仅限由医生销售或凭医嘱销售。**

警告： 标为“仅限骨水泥固定用途”的组件只能使用骨水泥植入。

请参见产品标签上的 CE 标记状态以及合法制造商。CE 标记只有在也出现在产品标签上时才有效。

下表列出 Howmedica Osteonics Corp. 产品标签上使用的缩写词：

术语	缩写	术语	缩写
字母编码	ALPH CDE	颈	NK
角	ANG	偏移	OFFST
度数	DEG or °	外径	OD
直径	DIA	右	RT ▶
超深	XDP	螺钉孔	SCR HLS
特大	XLGE	边侧	SDE
特小	XSM	尺寸	SZE
头	HD	小	SM
高	HT	标准	STD
内径	ID	锥形	TPR
内衬	INSR	厚度	THKNS
大	LGE	类型	TYP
左	◀ LFT	带有	W/
长度	LNTH	不带	W/O
中等	MED		

한글 Korean

HOWMEDICA OSTEONICS TRIATHLON TRITANIUM 완전 슬부 IFU

설명

Howmedica Osteonics Corp.의 완전 슬관절 Triathlon Tritanium 베이스플레이트는 Triathlon 프라이머리 고관절 대퇴부 콤포넌트, 경골부 삽입부, 그리고 슬개부 콤포넌트와 함께 사용하여 무릎 관절을 완전히 재건하기 위한 대체물로 고안되었습니다. 각 장치에 대한 특성은 제품 표지에 설명되어 있습니다. Triathlon Tritanium 베이스플레이트는 접합제를 사용 또는 사용하지 않고 적용하도록 표기되어 있습니다.

대퇴부 콤포넌트: Triathlon Tritanium 베이스플레이트는 Triathlon 십자인대 보존(CR) 및 십자인대 절제(후방 안정화 – PS) 디자인과 호환됩니다.

경골부 콤포넌트: Triathlon Tritanium 베이스플레이트는 십자인대 보존(CR), 후방 안정화(PS) 및 관절구 안정화(CS) 디자인에서 Triathlon 경골부 삽입부와 호환됩니다. 경골부 삽입부는 여러 종류의 두께와 다양한 압박 정도로 제공됩니다.

참고: Triathlon Tritanium 베이스플레이트는 임팩터 패드와 함께 제공됩니다. 임팩터 패드는 경골부 베이스플레이트 압입 단계에서만 사용해야 하고, 압입이 완료된 후에는 폐기해야 합니다. 임팩터 패드를 임플라트에 사용하지 마십시오.

슬개부 콤포넌트: 슬개부 치환 콤포넌트는 모든 플라스틱 대칭 및 비대칭, 그리고 메탈백 디자인에 사용할 수 있습니다. 슬개부 콤포넌트를 선택적으로 사용하십시오. Triathlon Tritanium 베이스플레이트는 모든 Triathlon 슬개부 콤포넌트와 호환됩니다.

재료

• ASTM F–75 코발트 크롬 합금	대퇴부 콤포넌트
• ASTM F–90 코발트 크롬 합금	경골부 삽입부용 고정 와이어
• ASTM F–1537 코발트 크롬 합금	대퇴부 페그
• ASTM F–136 티타늄 합금	경골부 콤포넌트
• ASTM F–67 CP 티타늄	경골부 콤포넌트
• ASTM F–1185 인산 칼슘	대퇴부 콤포넌트, 슬개부 콤포넌트
• ASTM F–648 초고분자량 폴리에틸렌	경골부 베어링 삽입부, 슬개부 콤포넌트

적응(증)

일반 완전 슬부 인공 관절술(TKR)에 대한 적응증:

- 무릎의 통증, 장애로 인한 관절염의 원인은 다음과 같습니다: 비염증성 퇴행성 관절염 (뼈관절염, 외상성 관절염 또는 무혈성 괴사 포함), 류마티스 관절염 또는 외상 후 관절염.
- 외상후 무릎 관절 배치나 기능의 상실
- 인대 구조가 적합한 기능과 안정성으로 회복될 가능성이 있는 중등 내반족, 외반족, 혹은 굴곡 기형.

- 성공적이지 못한 슬부 교체 또는 기타 처치에 대한 교정.
- 표준 골절 관리 기법으로 안정화시킬 수 없는 대퇴골 원위부 및/또는 근위 경골의 골절

Triathlon Tritanium 베이스플레이트는 접착제를 사용 또는 사용하지 않는 경우에 사용합니다.

후방 안정화(PS) 콤포넌트용 추가 적응증

- 증가된 압박으로 이식 베어링 표면의 기하학적 배열을 요구하는 인대의 불안전성.
- 후방 십자 인대의 부재나 마비.
- 심각한 무릎 관절의 전후 불안정성.

금기

- 슬부 관절 내부나 주위의 활성 또는 의심이 가는 잠재 감염.
- 감염 부위가 먼 경우 혈행성 감염이 이식 부위로 번질 수 있습니다.
- 보철 불안정, 보철 고정 실패 또는 수술후 진료의 합병증으로 인하여 치명적인 위험을 초래할 수 있는 정신적 혹은 신경근육성 장애.
- 질병 및 감염 또는 보철에 안정적인 지지 및 고정이 결여된 기존 임플란트에서 기인한 뼈 스톡의 손상.
- 골격의 미성숙.
- 결인대 구조나 기능 부재에 따른 심각한 이차적 무릎 관절 불안정성.
- 비만. 과체중이나 비만 환자는 장치의 고장을 유발할 수 있는 보철의 과부하를 초래할 수 있습니다.

주의

- 의사는 재건 수술의 한계와 적절한 고정과 회복 전까지 이식물에 전체 체중을 가하지 않게 보호해야 하는 필요성을 환자에게 알려야 합니다. 관절 대치에 영향을 주는 과도한 운동이나 외상은 의지 이식물의 이완, 파열 그리고/혹은 마모에 의해 재건 수술의 실패를 초래할 수 있습니다. 콤포넌트의 이완은 마모 입자가 더 많이 생기게 할 뿐만 아니라 교정 수술을 실패하게 만드는 뼈 손상을 초래할 수 있습니다.
- 환자는 활동을 억제하고 대치된 관절에 불필요한 압박을 주지 않도록 조심해야 하며 추적 검사와 진료에 관한 의사의 지시를 따라야 합니다.
- 수술의는 장치의 유한한 사용 수명과 이식 수술 후 보호에 필요한 사항 등을 포함하여 잠재적인 부작용에 관해 환자에게 경고를 해야합니다. 환자는 장치가 정상적인 건강한 관절의 유연성, 강도, 신뢰성 또는 내구성을 복제하는 것이 아니고 힘이 가해지는 운동이나 외상에 의해 이식물이 파손되거나 손상될 수 있다는 것을 알아야 합니다.
- 완전 슬부 구성부품의 적절한 선택, 배치 및 고정은 임플란트 사용 수명에 영향을 주는 중대한 요인입니다. 모든 보철 임플란트와 마찬가지로, 이 콤포넌트들의 내구성도 다양한 생물학적, 생물기계적 및 기타 외부 요인들의 영향을 받으며, 이로 인하여 사용 수명이 제한됩니다. 따라서 이 제품의 적응증과 금기, 주의 및 경고를 엄격히 준수하는 것이 사용 수명을 연장하는데 반드시 필요합니다.

활용 및 이식

- 크기의 결정, 시험 감소 및 운동 범위의 평가에는 권장하는 시험용 콤포넌트를 반드시 사용하여, 실제 임플란트와 멸균 포장을 보전해야 합니다.
- 수술전에 콤포넌트 크기와 스타일의 예측에 도움이 되는 방사선 촬영용 템플릿이 제공됩니다.
- 임플란트 부위에서 골세편, 뼈 접작제 조각 및 금속 파편을 제거하여 파편들로 인해 임플란트의 관절면이 급속히 마모되지 않도록 주의해야 합니다.
- Howmedica Osteonics Corp.사의 수술 소견설명서는 처치에 대한 추가 설명을 제공합니다.
- 특정 제품에 대한 호환성에 관해서는 제품 표지를 참고하십시오. 일반적으로 다음 사항이 적용됩니다:
  - PS 대퇴부에는 PS 경골부 베어링만 사용
  - CR 대퇴부는 CR 경골부 베어링과만 사용
  - PS 또는 CR 대퇴부에는 CS 경골부 베어링만 사용

환자를 위한 정보

- 의사는 환자에게 재건 수술의 한계와 적절한 고정과 회복 전까지 이식물에 전체 체중을 가하지 않게 보호해야 하는 필요성을 인식시킵니다. 관절 대치에 영향을 주는 과도한 운동이나 외상은 의지 이식물의 이완, 파열 그리고/혹은 마모에 의해 재건 수술의 실패를 초래할 수 있습니다. 콤포넌트의 이완은 마모 입자가 더 많이 생기게 할 뿐만 아니라 교정 수술을 실패하게 만드는 뼈 손상을 초래할 수 있습니다.
- 환자는 활동을 억제하고 대치된 관절에 불필요한 압박을 주지 않도록 조심해야 하며 추적 검사와 진료에 관한 의사의 지시를 따라야 합니다.
- 의사는 환자에게 수술의 위험에 대해 주의를 주고 잠재적인 부작용에 대해서도 숙지시킵니다. 환자는 장치가 정상적인 건강한 관절을 복제하는 것이 아니고 힘이 가해지는 운동이나 외상에 의해 이식물이 파손되거나 손상될 수 있으며 장치는 유한한 수명을 가지고 향후 교환해야 할 수도 있다는 것을 알아야 합니다.
- 일상 생활에서 일과성 균혈증이 발생할 수 있습니다. 치과 치료, 내시경 검사 그리고 기타 작은 수술 절차는 일과성 균혈증과 관련이 있을 수도 있습니다. 이식 부분에 감염을 예방하려면, 수술 전이나 후에 항생제 예방법을 사용하는것이 필요할 수 있습니다.

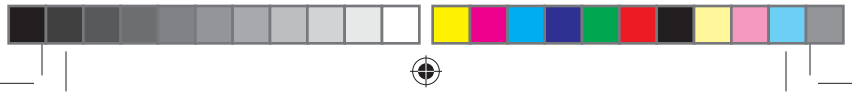
경고

- 손상되거나 잘못 취급된 임플란트는 모두 폐기처분 하십시오.
- 임플란트는 외관상 손상되지 않는 것처럼 보이더라도 절대로 재사용하지 마십시오.
- 임팩터 패드를 주입하지 마십시오. 임팩터 패드는 경골부 압입 단계에서만 사용해야 합니다. 압입 프로세스가 끝나면 즉시 제거하여 폐기하십시오.
- 이식물의 고광택 처리된 부분은 연마성이 있는 표면과 접촉되어서는 안됩니다.
- 베어링 부분은 조립 전 깨끗하게 유지하며 어떠한 이물질이 없도록 관리합니다.

- 이식물을 구부리거나 비틀면 피로 강도를 저하시켜 부하 시 고장을 초래할 수 있습니다.
- 삽입물에 있는 금속 고정 링은 조립체의 안전에 매우 중요하므로 만지거나 제거해서는 안됩니다. 금속 고정 와이어가 손상되었거나 잘못 취급된 경골부 베어링 삽입물은 폐기하십시오. 이 조립체를 함부로 다루는 경우 고정 장치의 기능에 영향을 줄 수 있습니다.
- 모서리가 날카로운 정형외과 장치의 취급 시 수술용 장갑이 절단되지 않도록 주의합니다.
- 명시된 사항을 제외하고는, Howmedica Osteonics Corp.식회사는 Howmedica Osteonics의 완전 슬부 콤포넌트를 다른 제조업체의 완전 슬부 콤포넌트와 함께 사용하지 않도록 강력히 권장합니다. 이러한 사용은 혼합 콤포넌트 임플란트의 성능과 관련하여 Howmedica Osteonics Corp.는 일체의 책임을 지지 않습니다.
- Howmedica Osteonics Corp.식회사는 Howmedica Osteonics 완전 슬부 콤포넌트를 다른 제조회사의 뼈 나사와 함께 사용하지 말 것을 강력히 권장하는 데, 이는 나사 머리와 나사 시트의 구성에 차이가 있기 때문입니다.
- 완전 슬부 콤포넌트를 의도적으로 제거하려면, 절삭용 버와 얇고 좁은 절골도를 주의해서 사용하며 힘을 조절하면 가능합니다.
- 금속 베이스 플레이트에 조립된 플라스틱 경골부 삽입물을 의도적으로 제거하는 경우 플라스틱 삽입물이 파괴될 수 있습니다. 삽입물 제거시 경골부 베이스 플레이트의 표면에 흠집이나 홈이 생기지 않도록 주의해야 합니다.
- 멸균 포장에 문제가 있는 제품은 공급자에게 반품하십시오. **재멸균하지 마십시오.**

부작용

- 완전 슬부 대치 콤포넌트의 기대 수명은 추정하기 어렵지만, 유한합니다. 이 콤포넌트들은 기동성의 복원이나 통증의 감소를 목적으로 신체에 삽입되는 이물질로 제작됩니다. 하지만, 이러한 장치에 영향을 주며 생체 평가가 불가능한 다수의 생물학적, 기계적 및 물리화학적 요인들로 인해, 콤포넌트들을 통한 활동 수준에는 한계가 있고 정상인의 건강한 뼈와 같은 기능을 수행하기에는 무리가 있습니다. 외과의사는 이 장치의 수명에 관해 환자들이 현실적인 기대감을 갖도록 설득해야 합니다.
- 대퇴부, 경골부, 혹은 슬개부 보철의 전위는 환자의 부적절한 활동이나 외상 또는 생물기계적 사항에 의해 발생할 수 있습니다.
- 완전 슬부 대치 콤포넌트는 느슨해질 수 있습니다. 조기에 발생하는 기계적인 느슨함은 초기의 불충분한 고정, 잠재 감염, 혹은 보철에 대한 조기 부하, 콤포넌트 부정형, 혹은 외상에 의해 초래될 수 있습니다. 추후의 느슨함은 외상, 감염, 골용해 등의 생물학적 합병증, 뼈의 미란 및/또는 통증을 수반할 수 있는 기계적 문제도 초래할 수 있습니다.
- 경골부, 대퇴부 그리고 슬개부 콤포넌트를 포함한 완전 슬부 콤포넌트의 피로 파단이 작은 비율이지만 발생했습니다. 하부 뼈의 부적절한 지지 혹은 콤포넌트 고정 부족으로 인해 슬부 콤포넌트의 파단이 발생할 수 있습니다.



- 말초 신경병증, 신경 손상, 순환계 손상이 초래될 수 있고 이소성 뼈가 형성될 수 있습니다.
- 모든 완전 관절 치환술에는 심각한 합병증이 초래될 수 있습니다. 이러한 합병증에는 비뇨생식기 장애, 위장 장애, 혈전 등의 혈관 장애, 색전 등의 기관지폐 장애, 심장마비나 사망이 포함되지만 이로써 제한되지는 않습니다.
- 폴리에틸렌 콤포넌트의 마모가 발생할 수 있으며 뼈의 재흡수 작용과 완화, 감염에 의한 것으로 밝혀졌습니다.
- 관절 대치 이후 금속 민감성 반응이 보고되었습니다.
- 부작용으로 인해 재수술, 교정, 해당 관절의 고정 및/또는 사지의 절단이 필요할 수 있습니다.
- 연부 조직의 약화 및/또는 이완은 콤포넌트의 불일치와 연관되는데, 이 경우 임플란트가 조기에 마모되거나 제대로 착상되지 않을 수 있습니다.
- 모든 임플란트 장치에서는 보철 콤포넌트 주위에 자각증상이 없는 국부적 뼈의 재흡수(골용해)가 발생할 수 있으며, 이는 시멘트 입자, 금속, 초고분자량 폴리에틸렌(UHMWPE) 및/또는 세라믹과 이물질이 작용하여 나타난 결과입니다. 콤포넌트들 사이나 콤포넌트와 뼈 사이의 상호작용에 의해 입상 물질이 생성되며, 일차적인 마모 기전은 접착, 접촉 마모 및 피로입니다. 또한, 입자는 다른 물체와 접촉 시 마모되어 생성될 수 있습니다. 골용해는 앞으로 합병증을 유발할 수 있으므로, 이러한 경우 보철 콤포넌트의 제거와 치환이 필요하게 됩니다.
- 정상적인 사용과 시간의 경과에 따라서 금속 및 폴리에틸렌 콤포넌트로부터 매우 작은 크기의 입자가 떨어져 나올 수 있다고 알려져 있습니다. 대부분의 부스러기들이 연관 관절에 남거나(예: 활막에 들어감) 주변의 피부 조직에 둘러싸이더라도, 미세 입자들은 관절 밖으로 이동하여 신체의 다른 부분으로 옮겨갈 수 있습니다. 현재, 이런 콤포넌트에서 생성될 수 있는 부스러기 및 미세 입자들에 관해 명확한 이유는 밝혀지지 않았습니다. 미세한 부스러기 입자들은 신체를 통해 방출될 수 있고, 경우에 따라 림프절 및 신체의 다른 부위에 축적되는 것으로 알려져 있습니다. 아직까지 이런 입자들로 인해 심각한 의학적 합병증이 보고된 적은 없었지만, 신체 속으로 이전 및/축적되는 경우는 여러 문헌에 언급되어 있습니다. 이러한 장치가 이식된 환자에 대한 추적 시간이 길지 않고 현재 이러한 장치가 비교적 젊은 환자에 의해 사용되고 있어서 앞으로 오랜 기간 동안 신체에 남아 있을 것이므로, 이러한 입자에 의한 장기적 영향에 대해서는 알려진 바가 없습니다. 그러나 장기적 영향에는 이론적으로 다음이 포함될 수 있습니다:
  - **암:** 현재 금속이나 폴리에틸렌 부스러기와 암을 연결시키는 어떠한 과학적 증거도 존재하지 않습니다. 그러나 그러한 가능성을 배제할 수 없습니다.
  - **림프절증 및 다른 조직/기관에서의 축적 :** 마모에 의한 부스러기가 림프절(근위 및 원위)에 축적된 것이 몇 차례 보고되었습니다. 이러한 축적에 의한 합병증이나 질병이 보고된 적은 없지만, 그 존재를 인식하여 진찰해야 하며 암 등의 병변과 혼동해서는 안 됩니다.

- **전신성 질병:** 부스러기의 이동과 아직 지정되지 않은 전신 영향 사이에 연관이 있을 수 있다는 추측이 있습니다. 일부의 장기적 영향이 장래에 발현될 수 있지만, 부스러기의 이동과 전신성 질병 사이의 관계를 시사하는 과학적 자료가 매우 적기 때문에, 이러한 장치가 제공하는 혜택이 이론상의 장기적 영향에 대한 위험 가능성 보다 훨씬 크다고 여겨집니다.

자기 공명 영상(MRI)과의 상호 작용

트라이애슬론 슬부 시스템은 MR 환경에서 안전 및 호환성에 대한 평가가 이루어 지지 않았습니다. 트라이애슬론 슬부 시스템은 MR 환경에서 가열이나 이동에 대해서 테스트 되지 않았습니다.

멸균

- 이 완전 슬부 콤포넌트는 감마 방사선 혹은 과산화수소 가스 플라즈마에 의해 멸균되었습니다. 포장 라벨에 표기된 멸균 방법을 참조하시오.
- 모든 멸균 제품의 포장은 개봉 전에 멸균 포장에 결함이 없는지 검사해야 합니다. 결함이 있다면, 그 제품은 멸균되지 않은 것으로 간주해야 합니다. 콤포넌트 사용 전에 멸균 포장을 열지 않아도 되도록 특수 시험용 보철을 제공하고 있습니다.
- 콤포넌트의 오염이 발생하지 않도록 주의해야 합니다. 멸균이 되지 않거나 오염된 제품은 모두 폐기하십시오.
- 포장이 개봉되었으나 제품을 사용하지 않은 경우, 콤포넌트를 재멸균해서는 안되며, 폐기하거나 공급자에게 반송해야 합니다.
- 포장이 이 날짜 이후로 유효하지 않기 때문에 표지에 표시된 만료 날짜 후에는 장치를 사용하지 않아야 합니다.
- 일회용 장치는 외식할 수 없으며 따라서 재이식도 불가능합니다. 이 작업으로 발생하는 물리적 힘이 장치의 물리적 무결성, 치수 및/또는 표면 마감을 손상시킬 수 있기 때문입니다. 또한 청소 및 재멸균 절차가 확인되지 않았기 때문에 장치를 재사용하는 경우 멸균 상태를 보장할 수 없습니다.

주의: **미국 연방법은 이 장치를 면허 소지 의사에 의해서 또는 그의 명령에 의해서만 판매하도록 제약하고 있습니다.**

경고: '시멘트 전용' 으로 표기된 콤포넌트는 반드시 뼈시멘트와 함께 이식되어야 합니다.

CE 표시 상태와 법적 제조업체에 대해서는 제품 라벨을 참조하십시오. CE 표시는 제품 라벨에 있을 때에만 유효합니다.

다음 표는 Howmedica Osteonics Corp. 식회사의 제품 표기에 사용되는 약어 목록입니다.

용어	약자	용어	약자
알파 코드	ALPH CDE	경부	NK
각도	ANG	오프셋	OFFST
정도	DEG or °	외부 지름	OD
지름	DIA	우	RT ▶
더 깊은	XDP	나사 구멍	SCR HLS
더 큰	XLGE	측면	SDE
더 작은	XSM	크기	SZE
두부	HD	작은	SM
신장	HT	기본	STD
내부 지름	ID	테이퍼	TPR
삽입	INSR	두께	THKNS
큰	LGE	유형	TYP
좌	◀ LFT	유	W/
길이	LNTH	무	W/O
중간	MED		

日本語 Japanese

HOWMEDICA OSTEONICSのTRIATHLON TRITANIUM人工全膝関節 取扱説明書

概要

Howmedica Osteonics Corp.の人工全膝関節システムは、膝関節の再建全置換のために、Triathlonプライマリー膝関節システムの大腿骨コンポーネント、脛骨インサート、および膝蓋骨のコンポーネントと併用するよう設計されている、Triathlon Tritanium (トライアスロン・トライタニウム)ベースプレートが含まれています。各器具固有の特長は、その製品ラベルで詳細されています。Triathlon Tritaniumベースプレートはセメントレス固定およびセメント固定の両方での使用に適用されます。

大腿骨コンポーネント: Triathlon Tritaniumベースプレートは、Triathlon十字靭帯温存型(CR)、および十字靭帯切除型(後方安定型 – PS)のものと適合性があります。

脛骨コンポーネント: Triathlon Tritaniumベースプレートは、Triathlon十字靭帯温存型(CR)、後方安定型(PS)、および顆部安定型(CS: condylar stabilizing)のものと適合性があります。脛骨インサートには広範囲の厚さと様々な抑制力のものがあります。

注記:　Triathlon Tritaniumベースプレートにはインパクターパッドが同梱されています。インパクターパッドは脛骨ベースプレート嵌入手順中のみに使用し、嵌入が完了したら破棄しなければなりません。インパクターパッドは植え込み用ではありません。

膝蓋骨コンポーネント:　: 膝蓋骨関節面再建コンポーネントは、純プラスチック製の対称・非対称、および金属で裏打ちされたのものがあります。膝蓋骨コンポーネントの使用は任意です。Triathlon Tritaniumベースプレートはすべてのの膝蓋骨コンポーネントと適合性があります。

材質

• ASTM F-75 コバルトクロム合金	大腿骨コンポーネント
• ASTM F-90 コバルトクロム合金	脛骨インサート用ロックワイヤ
• ASTM F-1537 コバルトクロム合金	大腿骨ペグ
• ASTM F-136 チタン合金	脛骨コンポーネント
• ASTM F-67 CPチタン	脛骨コンポーネント
• ASTM F-1185 リン酸カルシウム	大腿骨コンポーネント、膝蓋骨コンポーネント
• ASTM F-648 超高分子量ポリエチレン（UHMWPE）	脛骨ベアリングインサート、膝蓋骨コンポーネント

適用

人工膝関節全置換手術(TKR)の一般的な適用::

- 非炎症性変形性関節症(変形性関節炎、外傷後関節炎、または虚血壊死を含む)、リウマチ関節炎、または外傷後関節炎から発生する苦痛を伴い動かすことのできない膝関節の疾患がある場合。

- 外傷後の膝関節の形状および機能を損失した場合。
- 靭帯構造を適正な機能と安定性に戻し得るような中程度の内反、外反または屈曲の変形がある場合。
- 以前に行った人工膝関節置換、またはその他の手術が不成功に終わったためその調整を行う場合。
- 標準的な骨折管理法で安定できない大腿骨遠位部および/または脛骨近位部の骨折がある場合。

Triathlon Tritaniumベースプレートはセメントレス固定とセメント固定の両方での使用を意図しています。

後方安定型(PS)コンポーネントに関するその他の適用:

- 抑制力を強化した移植ベアリング表面幾何学形状を必要とする不安定な靭帯である場合。
- 後十字靭帯が不在であったり、機能が喪失している場合。
- 膝関節の前後方が著しく不安定な場合。

禁忌

- 膝関節内部または周囲に現在感染症があったり、潜伏性感染症の疑いがある場合。
- 移植部位に血行性散布の原因となる遠部感染病巣がある場合。
- プロテーゼの不安定化、プロテーゼの固定失敗、または術後の看護における合併症などの容認できない危険をもたらす精神的または神経筋肉的な障害がある場合。
- ボーンストックに疾病や感染症があったり、前回の移植のために適切にプロテーゼに支持、固定できない場合。
- 骨格が未熟な場合。
- 側副靭帯の完全性と機能の喪失により続発した膝関節に重度の不安定性がある場合。
- 肥満症のある場合。体重過多または肥満の患者はプロテーゼに負荷をかけることがあり、プロテーゼの固定失敗またはプロテーゼの故障につながることがあります。

術前注意

- 外科医は、患者に、再建術の限度と、適切に固定され治癒されるまでインプラントに完全に体重をかけないため保護が必要であることの2点について指導する必要があります。置換関節に影響する過度の活動および外傷は、プロテーゼインプラントの緩み、破損、摩耗により再建術の失敗に関係しています。コンポーネントが緩むと、摩耗粒子の発生増加や骨への損傷が生じ、修正手術の成功がさらに困難となります。
- 外科医は、活動を制限し、置換関節を不適切な応力から保護し、さらに術後のケアや治療について医師の指示に従うよう、注意を促す必要があります。
- 外科医は、器具の耐用寿命の有限性および術後におけるインプラントの保護の必要性を含め、潜在的な副作用について患者に警告すべきす。この器具が正常で健康な関節の柔軟性、強度、信頼性、または耐久性を再現するものでないこと、また過度の活動や外傷の結果インプラントが壊れたり損傷したりすることを外科医は患者に警告すべきです。

- 人工膝関節コンポーネントの適切な選択、設置、および固定は、インプラントの耐用年数に影響する重要な要因です。すべてのプロテーゼ移植について言えることですが、これらのコンポーネントは生物学的、生体力学的、および外来性のさまざまな要因に影響され、耐用年数が制限されます。したがって、耐用年数を最大限にするためにこの製品の適用、禁忌、術前注意、および警告に厳格に従うことが重要です。

使用と移植

- サイズの決定、試験的な整復、可動域の評価を行うために、推奨された試験的コンポーネントを必ず使用してください。そうすることで実際のインプラントおよび滅菌包装の完全性を維持することができます。
- コンポーネントサイズとスタイルの術前予測に役立つようX線撮影テンプレートが利用できます。
- 破片によるインプラントの関節面の磨耗が加速するリスクを減らすために、移植部位から骨欠片、骨セメント片、および金属破片を除去するよう注意してください。
- Howmedica Osteonics Corp.のSurgical Protocols（手術プロトコル）に、処置に関する詳細が記載されています。
- 特定の製品適合性については製品ラベルをご覧ください。一般に下記の事項が当てはまります。
  - PS大腿骨はPS脛骨ベアリングのみと併用してください。
  - CR大腿骨はCR脛骨ベアリングのみと併用してください。
  - PSまたはCRの大腿骨はCS脛骨ベアリングのみと併用してください。

患者のための情報

- 外科医は、患者に、再建術の限度と、適切に固定され治癒されるまでインプラントに完全に体重をかけないため保護が必要であることの2点について指導する必要があります。置換関節に影響する過度の活動および外傷は、プロテーゼインプラントの緩み、破損、摩耗により再建術の失敗に関係しています。コンポーネントが緩むと、摩耗粒子の発生増加や骨への損傷が生じ、修正手術の成功がさらに困難となります。
- 外科医は、活動を制限し、置換関節を不適切な応力から保護し、さらに術後のケアや治療について医師の指示に従うよう、患者の注意を促す必要があります。
- 外科医は、手術の危険性および可能な副作用について患者に警告してください。この器具が正常で健康な関節と同じではないこと、過度の活動や外傷の結果インプラントが壊れたり損傷したりすること、さらにこの器具には有限な使用寿命があり将来置換えの必要があることを、患者に警告しなければなりません。
- 日常生活において一過性菌血症が発生することがあります。歯科処置、内視鏡検査、およびその他の小手術も一過性菌血症と関連付けられています。移植部位における感染を防ぐには、そのような手順前後に抗生物質による予防法の使用が望ましいことがあります。

警告

- 損傷があったり、取り扱いを誤ったインプラントは処分してください。

- 損傷がないように見えても、絶対にインプラントは再使用しないでください。
- インパクターパッドを植え込まないでください。インパクターパッドは脛骨嵌入手順中のみに使用するためのものです。嵌入手順後は直ちに取り出し廃棄してください。
- 研磨済みベアリング部分は固い表面や摩耗性表面とは接触させないでください。
- 組立て前に、必ずベアリング部分をきれいにし、微粒子がついていないようにしてください。
- インプラントを変形したり折曲げたりすると耐疲労強度が減少し、負荷がかかった際に故障の原因となる場合があります。
- インサート上の金属製保持ワイヤはアセンブリの固定に重要なので、いじったり取り外したりしないでください。金属製保持ワイヤが損傷していたり誤った取り扱いがなされたりした場合は、脛骨ベアリングインサートを廃棄してください。このアセンブリをみだりにいじると保持機構が正常に機能しなくなる可能性があります。
- 鋭利な整形外科器具を取り扱う際には外科用手袋に穴が開かないように注意してください。
- 特記している場合を除き、Howmedica Osteonics Corp.は他社の人工全膝関節コンポーネントをHowmedica Osteonicsの人工膝関節コンポーネントと併用することは是非とも避けるようにお願いしています。そのような併用の結果発生する混合コンポーネントのインプラントの性能に関してHowmedica Osteonics Corp.は一切責任を負いません。
- Howmedica Osteonics Corp.は、ネジ頭とネジ台座の構造に違いがあるため、他社の骨ネジをHowmedica Osteonicsの人工全膝関節コンポーネントと併用することは是非とも避けるようにお願いしています。
- 人工全膝関節コンポーネントを故意に除去するには、切断バーおよび薄型で幅の狭い骨切りのみを注意して使用し、慎重に引っぱっると摘出できます。
- プラスチック製脛骨インサートを金属製ベースプレートに組み込んだ後で故意に取り外そうとするとプラスチック製インサートは壊れます。インサートを取り外す際、脛骨ベースプレートの表面に傷を付けないように気を付けてください。
- 無菌バリアに欠陥のあるものはすべて供給業者に返品してください。**再度滅菌しないでください**。

副作用

- 膝関節全置換コンポーネントの耐用寿命の予測は困難ですが、永久ではありません。これらのコンポーネントは可動性の回復および痛みの減少のために体内に設置される異物でできています。しかし、これらのコンポーネントに影響を与え、体内で評価できない生物学的、機械的、および生理化学的な要因のために、コンポーネントが通常の健康な骨にかかる活動と負荷に無限に耐えるものと期待することはできません。外科医は患者に器具の耐用寿命に対して非現実的な期待を持つべきではないことを助言すべきです。
- 不適切な患者の活動、外傷、またはその他の生体力学的配慮事項により人工の大腿骨、脛骨、または膝蓋骨のプロテーゼの転位が起こる場合があります。
- 人工膝関節コンポーネントの緩みが生じることがあります。初期における不適切な固定、潜在的な感染、早期のプロテーゼ負荷、コンポーネントの不良配列、または外傷から早期の機械的緩みが生じることがあります。外傷、感染、骨溶解を含む生物学的合併症、または

機械的な問題から後期の緩みが生じることがあり、その結果骨の浸食、痛みが生じることがあります。

- わずかな割合ですが、脛骨、大腿骨、膝蓋骨のコンポーネントを含む膝関節コンポーネントの疲労破損が起こることがあります。膝関節コンポーネントの破損は、その下の骨の支持が不十分であるか、またはコンポーネントの固定が不良であるために発生することがあります。
- 末梢神経障害、神経損傷、血行障害、および異所性骨形成の弱体化が発生することがあります。
- 深刻な合併症はどんな人工関節全置換手術にも生じる可能性があります。これらの合併症には、尿生殖器障害、胃腸障害、血栓を含む血管障害、塞栓を含む気管支肺障害、心筋梗塞、または死亡などがありますが、これらだけには限定されません。
- ポリエチレン製コンポーネントの摩耗が生じたことがあり、文献によるとこれは骨の再吸収、緩み、および感染と関係があると報告されています。
- 関節置換後の金属過敏反応が報告されています。
- 副作用のために再手術、修正、関与した関節の関節固定術、手足の切断などが必要になることがあります。
- 軟組織の不均衡および/または弛緩はコンポーネントのマルアライメントに関係しており、その結果インプラントの早期磨耗および/または故障につながる可能性があります。
- すべてのインプラントについて該当することですが、セメント、金属、超高分子量ポリエチレン（UHMWPE）や、セラミックの微粒子に対する異物反応の結果として、無症候性、局所進行性骨吸収（骨溶解）がプロテーゼコンポーネント周囲に発生することがあります。微粒子は、おもに粘着、剥離、および疲労の摩耗機構によるコンポーネント同士、およびコンポーネントと骨の間の相互作用により発生します。また、他との摩耗によっても発生します。骨溶解により、プロテーゼコンポーネントの緩みを含め、プロテーゼコンポーネントの除去および置換が必要となるような合併症が将来起こることがあります。
- 長期間において通常に使用していると、金属製およびポリエチレン製のコンポーネントから微小な粒子が出ることが知られています。この破片の大半は(滑膜内に含まれる)関連する関節内に残るか、または周囲の瘢痕組織によって閉じ込められますが、ミクロ粒子がその関節から身体の異なる部位に移動する可能性があります。現在、これらのコンポーネントから生じ得る破片およびミクロ粒子について解明されていない疑問があります。ミクロ粒子の破片が全身に播種(移動)し、場合によってはリンパ節および他の部位に蓄積する場合があることが示されています。これらの粒子が原因となる医学的に有意な合併症は今まで報告されていませんが、体内での移動や蓄積については文献で報告されてきました。これらの器具を使用する患者についての追跡調査期間が十分でなく、これらの器具を現在若年患者に使用しており、より長期にわたり体内に留まるという事実を考慮すると、これらの粒子による長期的な影響があったとしても、現時点ではその影響は不明であることを指摘する必要があります。理論上想定されている長期的影響には下記のものがあります。
  - **癌:** 現在、金属製およびポリエチレン製の破片と癌との関係についての科学的証拠はありません。しかし、その可能性を除外することはできません。

- **リンパ節症および他の組織や臓器内での蓄積:** (近位と遠位の)リンパ節内で磨耗による破片が蓄積したといういくつかの報告があります。これらの蓄積が原因となる医学的合併症または疾患過程は報告されていませんが、診断を円滑にし、疑わしい病巣や癌病巣などとの混同をさけるため、そのような蓄積が存在することを認識する必要があります。
- **全身性疾患:** 破片移動と未特定ではありますが全身的な影響との関連があるのではないかという推測が一部にあります。将来のある時点で一部の長期的影響が立証される可能性がありますが、破片移動と全身性疾患との関連を示す科学的データがほとんどないため、これらの器具の利点が、理論上推測された長期的影響についての潜在的危険性よりも明らかに勝ると思われます。

磁気共鳴画像診断装置(MRI)との相互作用

Triathlon膝関節システムは、磁気共鳴(MR)の存在する環境内での安全性および適合性について評価されていません。Triathlon膝関節システムは、磁気共鳴の存在する環境内での加熱および移動について試験されていません。

滅菌

- この全膝関節コンポーネントはガンマ放射線または過酸化水素ガスプラズマで滅菌されています。滅菌方法については包装ラベルをご覧ください。
- 開封前に無菌バリアに欠陥がないかすべての滅菌製品の包装を点検してください。そのような欠陥がある場合、製品は非滅菌と考える必要があります。コンポーネントの使用前に滅菌包装を一切開封しなくてもよいように、特別の試験的プロテーゼが利用できます。
- コンポーネントを汚染しないように注意してください。汚染した場合は、この製品を処分する必要があります。
- 包装が開封されているが、製品を使用していない場合、コンポーネントは再度滅菌することはできないので、処分するか供給業者に返品する必要があります。
- ラベルに記載の有効期限後は滅菌包装の妥当性について検証されていませんので、この日付後は器具を使用してはなりません。
- 再度の移植でかけられる物理的力によって器具の物理的完全性、特徴、表面加工などが損なわれる可能性があるので、単回使用器具は移植後、再度移植できません。また、洗浄・再滅菌手順の妥当性が確認されていないため、再使用器具の滅菌性は保証できません。

注意: 米国連邦法により本器具の販売または注文は医師によるもののみに限定されています。

警告: 「セメント固定専用」と記載されたコンポーネントは、骨セメントのみを併用して移植するようになっています。

CEマーク適合状況および法的製造業者については製品ラベルをご覧ください。CEマークは、製品ラベルにも表示されている場合に限り有効です。

下表はHowmedica Osteonics Corp. 製品ラベルで使用されている略語リストです。

用語	略語	用語	略語
アルファコード	ALPH CDE	ネック	NK
角度	ANG	オフセット	OFFST
度	DEG or °	外径	OD
直径	DIA	右	RT ▶
特に深い	XDP	ネジ穴	SCR HLS
特大	XLGE	側	SDE
極小	XSM	サイズ	SZE
ヘッド	HD	小	SM
高さ	HT	標準	STD
内径	ID	テーパー	TPR
インサート	INSR	厚さ	THKNS
大	LGE	タイプ	TYP
左	◀ LFT	付き	W/
長さ	LNTH	なし	W/O
中	MED		

Appendix H

Patient Retention Program

stryker

Orthopaedics

A prospective, post-market, multi-center study of the outcomes of the Triathlon Tritanium Knee System

Patient Retention Program

Program Details

The intent of this program is to provide birthday, holiday, and study surgery anniversary letters to the subjects who are part of the study. These letters will be provided to the site by Stryker Orthopaedics, they will thank the subject for his/her study participation and serve as a reminder to come in for the relevant follow-up visits.

Additionally, Stryker Orthopaedics is in the process of implementing a Patient Rewards Program as part of the Patient Retention Program. The details of this program will be made available when they have been finalized.

Participation in the Patient Retention Program is optional for each study site, and dependent on IRB approval at each site.

[Institution Address]
[City, State, Zip]
[Phone]

[Instutition Letterhead]

[Today's Date]

[Subject Name]
[Street Address]
[City, State, Zip]
[Phone]

Dear [Subject Name],

Congratulations!

Now that you have completed your [X] year visit in the study, you have earned your $[X] reward. Please find this reward enclosed. Thank you again for your continued participation in the Stryker Triathlon Tritanium Knee Outcomes Study and I look forward to seeing you at your future follow-up visits.

Sincerely,

[Study Coordinator Name]
[Institution Name]
[Street Address]
[City, State, Zip]
[Phone]
[Email}

[Institution Address]
[City, State, Zip]
[Phone]

[Instutition Letterhead]

[Today's Date]

[Subject Name]
[Street Address]
[City, State, Zip]
[Phone]

Dear [Subject Name],

Congratulations!

[Date] is the [X]-year anniversary of your [Left/Right] total knee replacement. Thank you for your continued participation in the Stryker Triathlon Tritanium Knee Outcomes Study, and I look forward to seeing you for your next follow-up visit.

Sincerely,

[Study Coordinator Name]
[Institution Name]
[Street Address]
[City, State, Zip]
[Phone]
[Email}

[Institution Address]
[City, State, Zip]
[Phone]

[Instutition Letterhead]

[Today's Date]

[Subject Name]
[Street Address]
[City, State, Zip]
[Phone]

Dear [Subject Name],

Happy Birthday! Thank you for your participation in the Stryker Triathlon Tritanium Knee Outcomes Study. I look forward to seeing you in the office for your future follow-up visits!

Sincerely,

[Study Coordinator Name]
[Institution Name]
[Street Address]
[City, State, Zip]
[Phone]
[Email}

[Institution Address]
[City, State, Zip]
[Phone]

[Instutition Letterhead]

[Today's Date]

[Subject Name]
[Street Address]
[City, State, Zip]
[Phone]

Dear [Subject Name],

Happy Holidays! Thank you for your participation in the Stryker Triathlon Tritanium Knee Outcomes Study. I look forward to seeing you in the office for your future follow-up visits!

Sincerely,

[Study Coordinator Name]
[Institution Name]
[Street Address]
[City, State, Zip]
[Phone]
[Email}

Appendix I

Component Listing

Cohort 1 (cementless) Study Device Component Listing:

Catalog Number
Triathlon Tritanium Tibial Baseplate
5536-B-100
5536-B-200
5536-B-300
5536-B-400
5536-B-500
5536-B-600
5536-B-700
5536-B-800
Triathlon Tritanium Asymmetric Patella
5552-L-299
5552-L-320
5552-L-350
5552-L-381
5552-L-401
Triathlon Tritanium Symmetric Patella
5556-L-319
5556-L-339
5556-L-360
5556-L-391

Cohort 1 (cementless) Compatible Ancillary Component Listing:

Catalog Number
Triathlon PS Beaded Femur with PA
5516-F-101
5516-F-102
5516-F-201
5516-F-202
5516-F-301
5516-F-302
5516-F-401
5516-F-402
5516-F-501
5516-F-502
5516-F-601
5516-F-602
5516-F-701
5516-F-702
5516-F-801
5516-F-802
Triathlon CR Beaded Femur with PA
5517-F-101
5517-F-102
5517-F-201
5517-F-202
5517-F-301
5517-F-302
5517-F-401
5517-F-402
5517-F-501
5517-F-502

5517-F-601
5517-F-602
5517-F-701
5517-F-702
5517-F-801
5517-F-802
Triathlon CR Conventional Polyethylene Tibial Inserts*
5530-P-X09**
5530-P-X11**
5530-P-X13**
5530-P-X16**
5530-P-X19**
Triathlon CR X3 Tibial Inserts*
5530-G-X09**
5530-G-X11**
5530-G-X13**
5530-G-X16**
5530-G-X19**
Triathlon CS Conventional Polyethylene Tibial Inserts*
5531-P-X09**
5531-P-X11**
5531-P-X13**
5531-P-X16**
5531-P-X19**
5531-P-X22**
5531-P-X25**
Triathlon CS X3 Tibial Inserts*
5531-G-X09**
5531-G-X11**
5531-G-X13**
5531-G-X16**
5531-G-X19**
5531-G-X22**
5531-G-X25**
Triathlon PS Conventional Polyethylene Tibial Inserts*
5532-P-X09**
5532-P-X11**
5532-P-X13**
5532-P-X16**
5532-P-X19**
5532-P-X22**
5532-P-X25**
Triathlon PS X3 Tibial Inserts*
5532-G-X09**
5532-G-X11**
5532-G-X13**
5532-G-X16**
5532-G-X19**
5532-G-X22**
5532-G-X25**

Cohort 2 (cemented) Control Device Component Listing:

Catalog Number
Triathlon Cemented Tibial Baseplate
5520-B-100
5520-B-200
5520-B-300
5520-B-400
5520-B-500
5520-B-600
5520-B-700
5520-B-800
Triathlon Symmetric Conventional Polyethylene Patella
5550-L-278
5550-L-298
5550-L-319
5550-L-339
5550-L-360
5550-L-391
Triathlon Asymmetric Conventional Polyethylene Patella
5551-L-299
5551-L-320
5551-L-350
5551-L-381
5551-L-401
Triathlon Symmetric X3 Patella
5550-G-278
5550-G-298
5550-G-319
5550-G-339
5550-G-360
Triathlon Asymmetric X3 Patella
5551-G-299
5551-G-320
5551-G-350
5551-G-381
5551-G-401
Triathlon CR Cemented Femur
5510-F-101
5510-F-102
5510-F-201
5510-F-202
5510-F-301
5510-F-302
5510-F-401
5510-F-402
5510-F-501
5510-F-502
5510-F-601
5510-F-602
5510-F-701
5510-F-702
5510-F-801
5510-F-802
Triathlon PS Cemented Femur
5515-F-101

5515-F-102
5515-F-201
5515-F-202
5515-F-301
5515-F-302
5515-F-401
5515-F-402
5515-F-501
5515-F-502
5515-F-601
5515-F-602
5515-F-701
5515-F-702
5515-F-801
5515-F-802

*Both cohorts utilize the same tibial inserts.
**(X = 1,2,3,4,5,6,7 and 8)