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Orthopaedics

Restoration® Anatomic Dual Mobility (ADM) X3® Acetabular System Study

With Long Term Data Collection for the Accolade® II Hip Stem

CLINICAL PROTOCOL

A prospective, post-market, multi-center study of the

Restoration® ADM X3® Acetabular System

and the Accolade® II Hip Stem

Sponsor:	*Stryker Orthopaedics* *325 Corporate Drive* *Mahwah, NJ 07430* *201-831-5000*
Study Product:	*Restoration® ADM X3® Acetabular System* *Accolade® II Hip Stem*
Protocol Number:	*70*
510(k) Clearance Numbers:	*K072020 – October 18, 2007* *K093644 - December 18, 2009* *K103479 – March 21, 2011* *K120578 – March 29, 2012*

Version 3.0

Date: 2020-04-15

CONFIDENTIAL

Protocol Change History

Version	Description	Changed By
A	New	Veronica Lewis
B	Modified evaluation schedule, corrected references, clarified inclusion/exclusion criteria, updated statistical analysis, modified enrollment period to 24 months, modified Appendix B, and created Appendix E.	Christina Hawley
1.0	Removed Draft watermark, Updated Version number.	Christina Hawley
2.0	Added background and device information for the Accolade® II Hip Stem. Enrollment strategy modified as follows: • Enrollment will continue until 350 cases have received the Restoration ADM® X3® System (acetabular shell & insert) • Enrollment will include a minimum of 100 cases implanted with the Accolade® II Hip Stem (within the study population). Additional changes include: • Added EQ-5D • AP Femur x-ray view • Updated eCRF specifications to incorporate new device and questionnaire	Carinna D. Kison

Version	Description	Changed By
3.0	Updated the following sections and appendix by removing language regarding the old patient retention program and including information regarding the new patient stipend program. • **12.5 Potential Benefits to the Subject** • **15.3 Subject Stipends or Payments** • **Appendix E** Removed **Appendix G** as the study is no longer utilizing the patient stipend program to which it applied.	Ajay Rastogi

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List of Abbreviations

ADE	Adverse Device Effect
ADM	Anatomic Dual Mobility
AE	Adverse Event
AP	Anteroposterior
ASTM	American Society for Testing Materials
BMI	Body Mass Index
CFR	Code of Federal Regulations
CP	Commercially Pure
CRC	Clinical Research Coordinator
CSA	Clinical Study Associate
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
HA	Hydroxylapatite
HHS	Harris Hip Score
HIPAA	Health Insurance Portability and Accountability Act
ICMJE	International Committee of Medical Journal Editors
ID	Inner Diameter
IRB	Institutional Review Board
LEAS	Lower Extremity Activity Scale
NIDJD	Non-Inflammatory Degenerative Joint Disease
NIS	Nationwide Inpatient Sample
OD	Outer Diameter
PER	Product Experience Report
PI	Principal Investigator
QOL	Quality of Life
ROM	Range of Motion
SAE	Serious Adverse Event
SC	Study Coordinator
SCFE	Slipped Capital Femoral Epiphysis
SF-12	Short Form-12
SOMA	Stryker Orthopaedics Modeling &Analytics
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
UADE	Unanticipated Adverse Device Effect
UHMWPE	Ultra High Molecular Weight Polyethylene

Study Synopsis

Title	A prospective, post-market, multi-center evaluation of the clinical outcomes of the Restoration® Anatomic Dual Mobility (ADM) X3® Acetabular System with Long Term Data Collection for the Accolade® II Hip Stem
Short Title	Restoration® ADM X3® Study
Protocol Number	70
Phase	Post-market
Methodology	This study is a prospective, open-label, post-market, non-randomized, multi-center, clinical evaluation of the Restoration® ADM X3® Acetabular System for primary total hip arthroplasty (THA) with a cementless application in a consecutive series of patients who meet the eligibility criteria. The total enrollment goal for the study is 350 cases, all of which will receive the Restoration® ADM X3® Acetabular System. A minimum of 100 cases (within the study population) will receive the Accolade® II Hip Stem. The remaining cases will receive any other compatible Stryker femoral component. Data in the literature from other primary hip systems and similar dual mobility cups will be used as historical references.
Study Duration	1. Follow-up of each primary THA case to 10 years 2. Enrollment period of 24 months 3. Approximate 12-year total duration
Study Center(s)	Up to 12 investigational centers

Hypothesis	The success rate, defined as freedom from postoperative femoral head dislocation, for hips implanted with the Restoration® ADM X3® Acetabular System, is not 3.5% worse than hips implanted with other primary hip systems in the literature at 10 years. The success rate for other primary hip systems is approximately 97%. With a non-inferiority margin of 3.5%, the success rate for the Restoration® ADM X3® Acetabular System will be no less than 93.5% at 10 years.

Objectives	**Primary:** • To evaluate and determine the success rate, defined as absence of postoperative femoral head dislocation, at 10 years with the Restoration® ADM X3 ® Acetabular System. **Secondary**: • To evaluate all-cause revision and removal rates in the Restoration® ADM X3 ® Acetabular System and compare with those reported for other primary hip systems in the literature. • To compare function and health related quality of life (QOL) between the Restoration® ADM X3® Acetabular System and published results for other primary hip systems. The following outcomes measures will be used for this comparison: o Harris Hip Score (HHS) o Short Form-12 (SF-12) o Lower Extremity Activity Scale (LEAS) o EQ-5D 1-year, 2-year, 3-year, 4-year and 5-year HHS, SF-12 and LEAS will be compared to literature control with respect to improvement from preoperative scores. The EQ-5D data will be summarized and presented.

Objectives	• An additional Follow-Up Questionnaire will be administered annually in postoperative years 6-10 to assess patient satisfaction and pain, and to capture adverse events. This questionnaire will provide the survivorship information necessary to evaluate the primary objective of the study. • To review radiographic stability and complications between those implanted with the Restoration® ADM X3® Acetabular System and published results for other primary hip systems. Complication rates for psoas impingement and associated groin pain will be reviewed, as applicable.
Number of Cases	Cases will be enrolled until 350 cases have received the Restoration ADM® X3® Acetabular System. Additionally, a minimum of 100 cases (within the study population) will receive the Accolade® II Hip Stem.

Diagnosis and Main Inclusion/Exclusion Criteria	Inclusions: A. Patient has signed an IRB/EC approved, study specific Informed Patient Consent Form. B. Patient is a male or non-pregnant female, skeletally mature and age 18-75 years at time of study device implantation. C. Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD). D. Patient is a candidate for a primary cementless acetabular replacement. E. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

Diagnosis and Main Inclusion/Exclusion Criteria	Exclusions: F. Patient has a Body Mass Index (BMI) ≥ 40. G. Patient has an active or suspected latent infection in or about the affected hip joint at time of study device implantation. H. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device. I. Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's disease) leading to progressive bone deterioration. J. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days). K. Patient requires revision surgery of a previously implanted total hip replacement or hip fusion to the affected joint. L. Patient has a known sensitivity to device materials. M. Patient is a prisoner. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and pre-operative level of health, as well as the surgeon's experience and familiarity with the device. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.

Study Device	**Restoration® ADM X3® Acetabular System** Required Components : 1. Restoration® ADM Acetabular Shell 2. Restoration® ADM X3® Acetabular Insert The acetabular components must be used in a cementless application. Stryker femoral components must be used according to this study protocol. The following ancillary devices are permissible: • Stryker 28 mm femoral bearing head* • Stryker compatible femoral stems (minimum 100 cases implanted with Accolade® II Hip Stem) * The Restoration® ADM Acetabular Shell is **not intended for use** with the **Stryker LFIT™ Anatomic CoCr femoral bearing head larger than 28mm**.
Reference Therapy	Literature control

Statistical Methodology	**Primary:** The 90% confidence interval of the success rate will be computed at 10 years postoperative. For the non-inferiority comparison, the lower bound of this 90% confidence interval will be compared with 93.5%. For the superiority comparison, the lower bound of this 90% confidence interval will be compared with 97%. **Secondary:** o The Kaplan-Meier survival curve of revision/removal for the Restoration® ADM X3® Acetabular System (acetabular shell and insert) will be displayed. o A paired t-test will evaluate the changes in clinical and patient outcomes (HHS, SF-12, EQ-5D, and LEAS), preoperative to 5 years postoperative within the Restoration® ADM X3® Acetabular System (acetabular shell and insert) group, when data is available. In addition, the mean scores (HHS, SF-12, EQ-5D, and LEAS) over time will be tabulated, with standard deviation and 95% confidence intervals presented, if applicable. o The AE rates and radiographic data will be listed and tabulated at 10 years postoperative for the Restoration® ADM X3® Acetabular System group, with 95% confidence intervals presented, if applicable.

Evaluation Schedule

Evaluation	Preop X-rays (-1 yr) CRFs (-4 mos)	Intraop	6 weeks (± 3 wks)	1 year (± 2 mos)	2 years (± 2 mos)	3 years (± 3 mos)	4 years (± 4 mos)	5 years (± 4 mos)	6 years (± 4 mos)	7 years (± 4 mos)	8 years (± 4 mos)	9 years (± 4 mos)	10 years (±4 mos)
Inclusion/ Exclusion	X												
Demographics & Medical History	X												
Preoperative Functional Evaluation	X												
Surgical Details		X											
Postoperative Functional Evaluation			X	X	X	X	X	X		**Optional**			**Optional**
SF-12	X		X	X	X	X	X	X		**Optional**			**Optional**
LEAS	X		X	X	X	X	X	X		**Optional**			**Optional**
EQ-5D	X		X	X	X	X	X	X		**Optional**			**Optional**
Radiographs: Anteroposterior (AP) pelvis, AP femur, lateral	X		X	X	X	X	X	X		**Optional**			**Optional**
Follow-up Questionnaire									X	X	X	X	X

Functional Evaluation: The Functional Evaluations include the HHS, a subjective outcomes tool completed by the investigator that measures function, pain and motion.

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

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

EQ-5D: The EQ-5D is a standardized instrument for use as a measure of health outcome.

Follow-up Questionnaire: The Follow-up Questionnaire is a short patient questionnaire intended to provide information on dislocation, patient satisfaction, pain and whether or not there have been any revisions or removals of the study device since the last follow-up visit.

1 Introduction

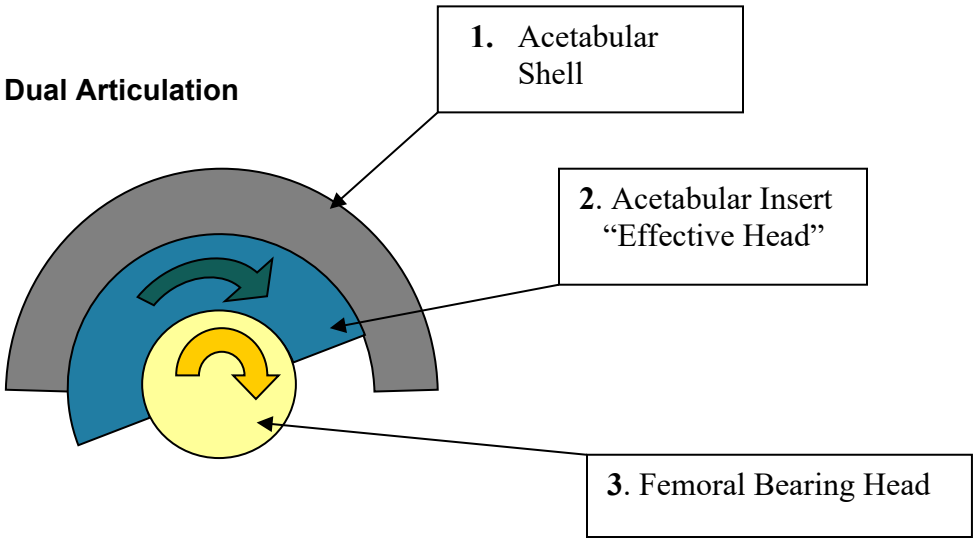
This document is a protocol for a human research study. This study will be conducted in compliance with the protocol, Good Clinical Practice (GCP) Standards, associated Federal regulations and all applicable research requirements.

1.1 Background

THA is one of the most clinically successful and cost-effective interventions in health care. Numerous surgeons have reported excellent long-term results in terms of reducing pain, improving function and QOL in patients with debilitating hip disease.[1]

The concept of dual mobility was first defined by Professor Gilles Bousquet in 1976 at the University Hospital of St. Etienne, France. This concept combines Charnley's low friction principle and the McKee-Farrar theory, implanting a large diameter femoral head to decrease the potential for instability. In the dual mobility system, the outer diameter (OD) of the mobile acetabular insert acts as an effective femoral head. The dual mobility system consists of a cementless metallic acetabular shell and a polyethylene insert which freely rotates within the shell and positively captures a prosthetic femoral head. The polyethylene insert functions like a bipolar head. Thus, there are two distinct articulations sharing the same center of motion.[2] See Figure 1 for a representative schematic.

Figure 1. Schematic of Dual Articulation



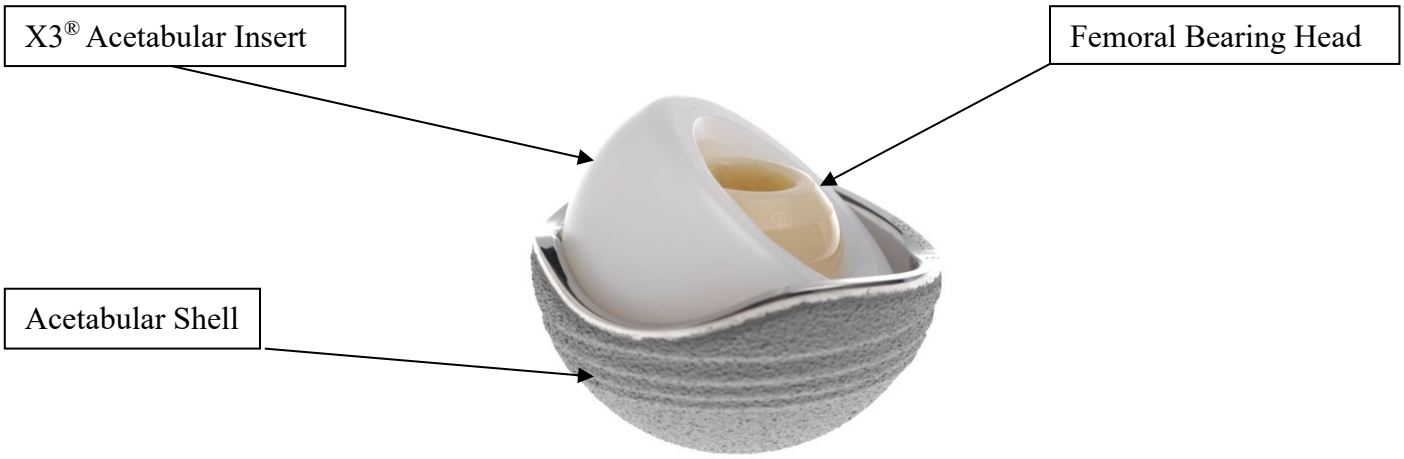
Articulation:

1 → 2: The first articulation occurs between the metal acetabular component and polyethylene acetabular insert.

2 → 3: The second articulation occurs between the polyethylene acetabular insert and the femoral bearing head. The femoral bearing head can be either metal or ceramic.

In the case of the Restoration® ADM X3® Acetabular System, the Restoration® ADM Acetabular Insert is composed of X3® Ultra High Molecular Weight Polyethylene (UHMWPE) which retains a femoral head. The convex surface of the X3® UHMWPE insert articulates on the highly polished concave surface of the cobalt chromium acetabular shell. The outer surface of the acetabular shell has a plasma sprayed Commercially Pure (CP) Titanium and Hydroxylapatite (HA) coating to establish initial good fixation. In addition, the rim of the Restoration® ADM Acetabular Shell has an anatomic cut-out to prevent conflict with the ilio-psoas tendon. See Figure 2. for a schematic of the Restoration® ADM X3® Acetabular System.

Figure 2. Restoration® ADM X3® Acetabular System



Dual mobility systems provide the advantages of the low friction THA with those of large femoral head diameters with the goals of increasing implant stability, reducing dislocation, increasing ROM and decreasing wear.

Dislocation is one of the most common complications following THA. Bozic et al.[3] used the NIS database to analyze clinical, demographic and economic data from 51,345 revision THA procedures performed in the United States between October 1, 2005 and December 31, 2006.

In this series, the most common cause of revision THA was dislocation/instability (22.5%) followed by mechanical loosening (19.7%) and infection (14.8%).[4] The 2007 Swedish hip arthroplasty registry reported that the most common cause for re-operation, aseptic loosening, declined by 6.2%, whereas increases were reported for fracture (+16.4%), dislocation (+14.1%) and deep infection (+6.6%) as causes for re-operation.[5]

Dual mobility systems have been successful in maintaining hip stability. Guyen et al.[6] reported a success rate of 94.5% in maintaining a stable hip with a dual mobility cup; no dislocation or subluxation was reported at 47.5 months. Philippot et al.[7] reported no early or late instability in a series of 384 cases who received a dual mobility cup, with a mean follow-up of 15 years.

In a dual mobility system the femoral head rotates within the polyethylene acetabular insert as with traditional designs, with the exception that during extended ROM, the UHMWPE insert is able to rotate within the cup. This configuration allows improved ROM before impingement.[8] One reason for groin pain postoperatively is the conflict of the anterior rim of the acetabular cup and the ilio-psoas tendon. Tracol et al.[9] evaluated the in vitro depth of the psoas ilio-pubic notch and developed the Restoration® ADM cup with a 3.5 mm anterior notch. The anterior cut-out is designed to mitigate conflict of the anterior portion of the cup and the psoas tendon.

The polyethylene insert utilized in the Restoration® ADM X3® Acetabular System is composed of X3® sequentially annealed UHMWPE. D'Antonio et al.[10] presented clinical data from 246 cases in a prospective multicenter study (Trident® X3® Acetabular Insert Study) in which all patients received X3® polyethylene inserts. The X3® inserts had a low linear wear rate of 0.008 mm/year at 5 years which represents a 58% improvement over a first-generation annealed highly cross-linked polyethylene.

Cementless acetabular components for THA became popular in the United States in the early 1980s, primarily due to poor long-term results with cemented cups. Superior radiographic performance has been reported for cementless cups as compared with cemented fixation.[11] The design of the Restoration® ADM Acetabular Shell is based on the Trident® PSL cementless cup. The cup is manufactured from wrought cobalt chromium alloy. The acetabular shell has a CP Titanium plasma sprayed and HA coating to establish initial good fixation. HA is a naturally occurring mineral form of calcium apatite that comprises 70% of human bone. HA is currently used as a biological coating on a variety of orthopaedic implants to stimulate bone ongrowth.

HA coating has over 15 years of published clinical history of use on the femoral stem showing 95.3% survivorship.[12] The coating is designed to provide a roughened surface texture. It is not an ingrowth surface but rather provides a surface roughness to the component.

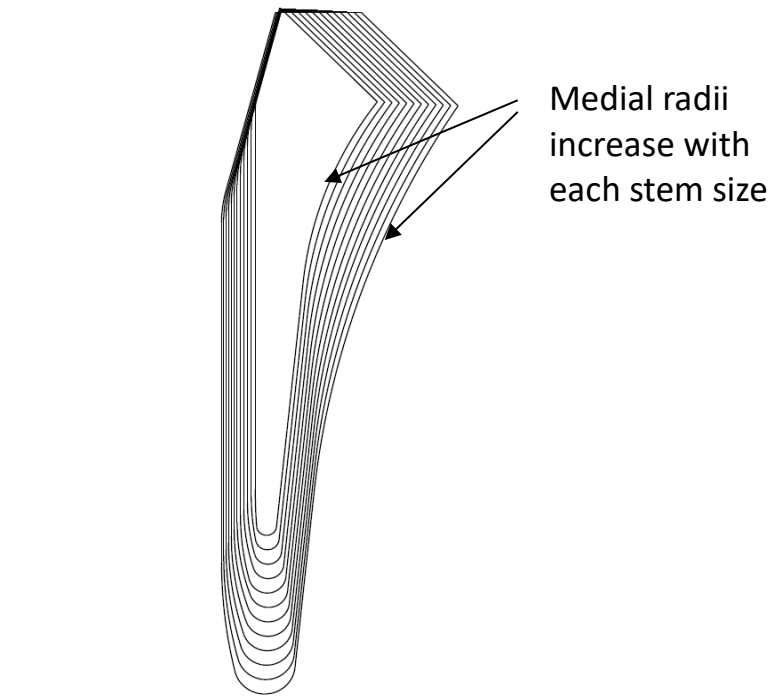
This clinical study is necessary to evaluate the success, defined as freedom from femoral head dislocation, of the Restoration® ADM X3® Acetabular System as compared to the reported success of other primary total hip systems and with products of similar dual mobility design. The objective of the study is to show that the study device performs no worse than similar devices at 10 years postoperative.

The study will also collect longitudinal data on the performance of the Accolade® II Hip Stem.

Cemented as well as cementless hip stems have shown good results in THA, even in younger patients.[13] Implant design may contribute to the success of an implant. A study conducted by Hozack et al.[14] showed that the Taperloc's flat, collarless, and wedge shaped design may have contributed to good femoral results. Additional biomechanical studies have shown excellent axial and rotational stability, and similar wedge shaped designs have also shown comparable results.[15,16,17]

A second generation of tapered stems was introduced to address distal fixation by shortening their first generation devices or by introducing entirely new stems. Accolade® II is different from other second generation stems in that CT scans were digitally studied in depth prior to generating the very first concepts. This was accomplished though SOMA, the unique Stryker Orthopaedics Modeling & Analytics technology. A study of 556 CT scans was conducted using SOMA and included a diverse group of men and women of different ethnic backgrounds and varying ages. The data was used to design a stem that would better fit the varying sizes and shapes of today's population[18,19]. The medial curvature of the stem was also changed to address the bone variations in different people. Accolade® II's size-specific medial curvature (seen in Figure 1) allows for a correctly proportioned stem that better fits a wider range of patients that maximizes the implant to bone surface contact. Additionally, the Accolade® II stem length has been optimized to accommodate all surgical approaches.

Figure 3. Size Specific Medial Curvature



Through micro-motion analysis that compared Accolade® II versus a simply shortened tapered wedge stem, it was determined that the size-specific medial curvature and correctly proportioned proximal to distal ratio results in an increase in stability. Contrary to this, if you simply shorten a first generation tapered wedge stem, the micro-motion of that stem increases or the stability decreases.

The Accolade® II Hip Stem was cleared for use under FDA 510(k) K103479 on March 21, 2011 and K120578 on March 29, 2012. The stem neck is designed with a Howmedica Osteonics V40 taper on the proximal end similar in design to the previously cleared Accolade® TMZF® Hip Stem (K994366, K020572, and K023102). The Accolade® II Hip Stem, like the Restoration® Modular Hip Stem (K022549, K051363) will be manufactured from Titanium (Ti-6Al-4V) Alloy with a commercially pure Titanium (CP Ti) and hydroxylapatite (HA) coating to establish good initial fixation.

1.2 Investigational Device

The Restoration® ADM Acetabular System was cleared for use under FDA 510(k) K072020 on October 18, 2007. The Restoration® ADM X3® Acetabular Insert was cleared for use under FDA 510(k) K093644 on December 18, 2009. The system consists of two components; an acetabular shell and an X3® UHMWPE acetabular insert.

The acetabular shell is manufactured from wrought cobalt chromium alloy with a CP Titanium and HA coating and is intended for cementless use. The inner surface of the cup is highly polished. The outer geometry of the Restoration® ADM Acetabular Shell is based on Stryker's Trident® acetabular cups and has a Peripheral Self Locking (PSL®) design. The rim of the Restoration® ADM Shell has an anatomic cut-out to prevent conflict with the ilio-psoas muscle.

The Restoration® ADM Acetabular Insert is composed of Stryker Orthopaedics sequentially annealed UHMWPE, X3®. The inner diameter (ID) of the acetabular insert is compatible with any currently available Stryker 28 mm femoral head (except for the LFIT™ Anatomic CoCr femoral bearing head) and a Stryker compatible femoral stem.

The Restoration® ADM X3® Acetabular Shell is available in a left and right configuration and ranges in size from 46 to 64 mm, OD. The shell is coupled with the Restoration® ADM X3® Acetabular Insert, ranging in size from 40 to 58 mm, OD.

The Accolade® II Hip Stem is a non-porous coated femoral stem with a flat tapered wedge design intended to provide rotational stability. The stem is designed with an anterior and posterior groove running along its axis distally up to the mid stem region. The medial curvature on the stem is size-specific and increases with stem size to address variations in patients. The distal portion of the stem has a lateral relief and satin finish, while the neck region of the stem is polished.

The Accolade® II Hip Stem is available in 12 sizes ranging from size 0 through 11. Stem length ranges from 93 mm to 126 mm in 3 mm increments. The neck lengths of the Accolade® II Hip Stem range from 27 mm to 40 mm and are proportional relative to the different body geometry. Additionally, the necks are available in two angles (127° and 132°) that provide dual offsets.

1.3 Preclinical Data

The following bench tests were conducted with the Restoration® ADM X3® Acetabular System. In some instances, the predicate device, ADM with Duration®, was used as a comparison device:

Wear Testing

Testing was performed to evaluate the wear performance of the Restoration® ADM System with X3® acetabular inserts and compared to the Restoration® ADM System with Duration® acetabular inserts.

The Restoration® ADM System with X3® Acetabular Inserts wore at a volumetric rate of 0.6 ± 0.8 mm^3/mc (volume per million cycles) (R^2=0.7273) while the Restoration® ADM System with Duration acetabular inserts wore at a volumetric rate of 20.9 ± 9.0 mm^3/mc (R^2=0.999). This corresponds to a 97% reduction in wear rate for the X3® material.[a] This reduction rate is statistically significant compared to conventional polyethylene materials. Visual examination also showed no signs of mechanical or fatigue damage for both Duration® and X3® materials.

A multi-station hip joint simulator was used for wear testing. Each station consisted of fixtures accommodating the femoral head and acetabular insert, which were aligned along the same vertical axis. Testing was conducted in an anatomical orientation with the insert stationary and mounted in a superior position. Articulation was provided by the femoral head mounted below. A specimen chamber surrounded the assembly and allowed for lubrication. The specimens were lubricated with calf serum diluted with deionized water and Ethylenediaminetetraacetic acid. Refer to test report RD-09-079, entitled Hip Simulator Wear Evaluation of The

[a] Stryker Orthopaedics Restoration® ADM X3® 28 mm ID acetabular inserts made of X3® Gas Plasma Sterilized UHMWPE, show a 97% reduction in volumetric wear rate versus 28 mm ID Restoration® ADM Duration Gamma Radiation Sterilized UHMWPE. Both ADM constructs utilized a 54mm OD shell and the inserts were approximately 9.9 mm thick. Testing was conducted under multi-axial hip joint simulation for 5 million cycles using a 28mm CoCr modular femoral head articulating counterface and calf serum lubricant. Volumetric wear rates were 109.7±6.0 $mm^3/10^6$ cycles and -1.03 ± 3.8 $mm^3/10^6$ cycles for Duration and X3® polyethylene insert test samples. Although in-vitro hip wear simulation methods have not been shown to quantitatively predict clinical wear performance, the current model has been able to reproduce correct wear resistance rankings for some materials with documented clinical results. [1-3]

[1] Wang, A, et. al., *Tribology International*, Vol. 31, No. 1-3: 17-33, 1998.
[2] Essner, A. et. al., *44th Annual Meeting, ORS*, New Orleans, Mar. 16-19, 1998: 774.
[3] Essner, A. et. al., *47th Annual Meeting, ORS*, San Francisco, Feb. 25-28, 2001: 1007.

Restoration® ADM X3® Acetabular System, for detailed methods. The conclusion of the tests was as follows:

- The Restoration® ADM X3® Acetabular System shows a 100% reduction in total volume loss over the Restoration® ADM Duration® Acetabular System after wear testing under the same conditions.
- The Restoration® ADM X3® Acetabular System shows a 97% reduction in wear rate over the Restoration® ADM Duration® Acetabular System after wear testing under the same conditions. This level exceeds the 50% level required in the design input, verification and validation requirements.
- The Restoration® ADM Duration® Acetabular System compares favorably in terms of wear rate when compared to the same 28 mm ID Stryker Trident® N2VAC® liner. For this reason, this system may outperform a conventional acetabular bearing construct in terms of wear.
- Both X3® and Duration® Restoration ADM Acetabular Inserts showed no signs of mechanical or fatigue damage (cracks, etc) after 5 million cycles of testing.

Lever Out/Push Out Testing

Testing was performed on the worst case component of each material insert to compare the dislocation resistance of the inserts by characterizing their lever out and pull out strengths. The following smallest and thinnest available components were identified as the worst case from each material: X3® part number 1236-2-846 (28 mm ID/ 46 mm OD) & Duration® part number 1235-2-246 (22.2 mm ID/ 46 mm OD). Seventeen test samples were used for each material in both lever-out and pull-out tests. The results of the testing showed that the lever-out and pull-out resistance strengths of the worst case X3® Acetabular Insert were not less than the worst case Duration® Acetabular Inserts, meeting the test acceptance criteria. Ease of use with instrumentation was also identified to be similar between the X3® and Duration® Acetabular Inserts. Refer to test reports TR09-1014, entitled Comparative Lever-Out & Axial Pull-Out Testing of Restoration® ADM X3®, for detailed methods and results.

Contact Stress Analysis

The contact stress within the subject Restoration® ADM X3® Acetabular Inserts are comparable to those of its predicate Trident® X3® Acetabular Inserts.

Materials

The subject X3® and predicate Duration® Acetabular Inserts are manufactured from UHMWPE meeting American Society for Testing Materials (ASTM) Standard F648. The predicate Duration® Acetabular Insert device is fabricated from GUR 1050 UHMWPE. The X3® Acetabular Insert is manufactured from compression molded GUR 1020 polyethylene. Manufacturing changes have been made to the processing of the raw material to provide a sequentially crosslinked and annealed polyethylene material for use in the manufacturing of the inserts. See Table 1 for a summary of Duration® and X3® properties. Based on the comparative results below, the 1020 GUR is acceptable for use in combination with the Restoration® ADM Acetabular Shell for THA.

Table 1. Subject Polyethylene Properties

Property	Duration Polyethylene 1050 GUR Mean (Std. Dev.)	X3® Polyethylene 1020 GUR Mean (Std. Dev.)
UTS (MPa)	51.1 (3.3)	56.7 (2.1)
Yield Strength (MPa)	24.3 (0.5)	23.5 (0.3)
% Elongation	404 (16)	267 (7)
Density (kg/m^3)	929.2 (0.0)	939.2 (0.1)
% Crystallinity	56.7	61.7 (0.6)

The results of the bench top testing conducted for the new Restoration® ADM X3® Acetabular Inserts identified acceptance criteria was met.

The following bench tests were conducted with the Accolade® II Hip Stem:

- 127° Accolade® II Size 3 Neck Verification Testing (RD-10-095)
- 127° Accolade® II Size 0 Distal Body Verification Testing (RD-10-096)
- 127° Accolade® II Size 2 Neck Verification Testing (RD-11-022)

The results of the bench top testing conducted for the new Accolade® II Hip Stem 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 Restoration® ADM X3® Acetabular System and the Accolade® II Hip Stem.

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 hip replacement (THR) with the Restoration® ADM X3® Acetabular System as compared to the published results of primary THR systems. Success will be defined as absence of femoral head dislocation at 10 years postoperative. It is expected that the survivorship of the Restoration® ADM X3® Acetabular System group will be non-inferior to the survivorship reported in the literature for other primary THR systems.

2.1.2 Secondary

The secondary objectives of this study will be to evaluate all-cause revision and removal rates with the Restoration® ADM X3® Acetabular System and compare with those reported for other primary hip systems in the literature.

Additionaly, psoas impingement and associated groin pain, function and health-related QOL between the Restoration® ADM X3® Acetabular System and those reported in the literature for other primary hip systems and similar dual mobility cups on the market will be compared at postoperative time points.

Lastly, radiographic stability and complications between those implanted with the Restoration® ADM X3® Acetabular System and other primary hip systems in the literature will be reviewed.

Clinical Outcomes:

Clinical outcomes will be evaluated with the total HHS, including pain, motion and function, preoperatively and at the 6-week, 1, 2, 3, 4 and 5-year visits. Additional

HHS data will be obtained at the 7-year and 10-year time points at investigational sites that choose to bring their subjects in for these optional visits.

Patient Outcomes:

Pain, function and health related QOL will be compared between the Restoration® ADM X3® Acetabular System and reports in the literature for other primary THR systems and similar dual mobility cups on the market. The SF-12 is a 12 item patient self-assessment evaluating health and general well being. The LEAS is a tool that has been developed and validated to evaluate the level of patient activity. The EQ-5D is a standardized instrument for use as a measure of health outcome. These tools will be used to assess patient health-related QOL and will be collected preoperatively at the 6-week, 1, 2, 3, 4, and 5-year visits.

A Follow-Up Questionnaire will be administered annually in postoperative years 6-10 to assess patient satisfaction and pain, and to capture AEs. This questionnaire will provide the survivorship information necessary to evaluate the primary objective of the study. Patient outcomes data will also be obtained at the 7-year and 10-year time points at investigational sites that choose to bring their subjects back in for these optional visits, in addition to the required Follow-Up Questionnaire described.

Radiographic Outcomes:

To assess radiographic stability as compared with other primary THR systems and similar dual mobility cups, radiographs will be taken and collected in the AP pelvis, AP femur and lateral views for the preoperative, 6-week, 1, 2, 3, 4 and 5-year intervals. Additional radiographs will be obtained at the 7-year and 10-year time points at investigational sites that choose to bring their subjects back in for these optional visits.

The AP pelvis and AP femur view allow for observation of any conditions involving the sacral wings, iliac bones, ischium, pubis as well as the femoral head and neck. The lateral view allows for evaluation of the entire hip joint as well as the femoral head, neck and proximal shaft.[20] Suggested radiographic technique for the views required is included in Appendix A.

Radiographs will be evaluated by an independent reviewer throughout the course of the study. Radiographic analysis of the acetabular component will employ three zones (Zone 1 – Zone 3) in the AP view.[21,22] Radiographic analysis of the femoral component will employ seven zones (Zone 1 - Zone 7) in the AP views and seven zones (Zone 8 – Zone 14) in the lateral view. Numerous parameters will be reviewed by zone, including radiolucency, hypertrophy, condensation and migration. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width is defined as radiolucency present. Cases that present with migration of greater than 5 mm in any direction or at least 2 mm radiolucency in all zones will be considered radiographic failures.

2.2 Safety

All operative site events as well as all serious adverse events (SAEs), excluding elective procedures, will be collected and compared to published data. It is expected that the AE rates reported for the Restoration® ADM X3® Acetabular System will be comparable to those reported in the literature for other primary THR systems and similar dual mobility cups 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 will be employed. Radiographs will be assessed by an independent reviewer.

3.2 Number of Centers

Cases will be enrolled at up to 12 centers. The enrollment goal is 29 cases per center utilizing the Restoration® ADM X3® Acetabular System but will vary dependent upon the number of participating centers. Although a goal is presented, there is no maximum limit to the number of cases that a center may enroll. In the event that a center far exceeds the enrollment goal, Stryker may ask the center to cease enrollment so as not to skew the data. All participating centers will comply with the federal regulations regarding patient informed consent and Institutional Review

Board (IRB) or Ethics Committee (EC) approval. Non-compliance of a study center may result in termination of the center's participation in the study.

3.3 Number of Subjects

Cases will be enrolled until a total of 350 cases receive the Restoration® ADM X3® Acetabular System. Additionally, a minimum of 100 cases (within the study population) will receive the Accolade® II Hip Stem.

Stryker will monitor enrollment to ensure the enrollment goals for the Restoration® ADM X3® Acetabular System and the Accolade® II Hip Stem are satisfied.

3.4 Estimated Study Duration

The enrollment period is estimated to be a maximum of 24 months; cases will be evaluated as per the evaluation schedule until each case reaches 10 years.

To allow for a learning curve with the use of the device, enrollment of cases into the study will commence when five cases have been completed at the center using the Restoration® ADM X3® Acetabular System.

4 Eligibility

The following criteria will be 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 pre-operative level of health, as well as the surgeon's experience and familiarity with the device. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.

4.1 Inclusion Criteria

A. Patient has signed an IRB/EC approved, study specific Informed Patient Consent Form.
B. Patient is a male or non-pregnant female, skeletally mature and age 18-75 years at time of study device implantation.

C. Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
D. Patient is a candidate for a primary cementless acetabular replacement.
E. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.

4.2 Exclusion Criteria

F. Patient has a Body Mass Index (BMI) ≥ 40.
G. Patient has an active or suspected latent infection in or about the affected hip joint at time of study device implantation.
H. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device.
I. Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's disease) leading to progressive bone deterioration.
J. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days).
K. Patient requires revision surgery of a previously implanted total hip replacement or hip fusion to the affected joint.
L. Patient has a known sensitivity to device materials.
M. Patient is a prisoner.

5 Subject Enrollment

5.1 Treatment Assignment

All subjects will receive the Restoration® ADM X3® Acetabular System with a minimum of 100 cases (within the study population) that will receive the Accolade® II Hip Stem.

Stryker will monitor enrollment closely to ensure that the enrollment goals of Restoration® ADM X3® Acetabular System and the Accolade® II Hip Stem are satisfied.

5.2 Randomization

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

6 Device Description

6.1 Study Device

The Restoration® ADM X3® Acetabular System and the Accolade® II Hip Stem have been cleared for use in the United States; therefore, this study is considered a post-market assessment. All cases in this study will receive the Restoration® ADM X3® Acetabular System which consists of two components, an acetabular cup and an X3® UHMWPE acetabular insert.

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

- Compatible Stryker femoral stem (minimum of 100 Accolade® II Hip Stems)
- 28 mm Stryker femoral head*

The acetabular cup is manufactured from wrought cobalt chromium alloy with a CP Titanium and HA coating and is intended for cementless use. The inner surface of the cup is highly polished. The outer geometry of the Restoration® ADM Acetabular Shell is based on Stryker's Trident® Acetabular Shell and has a PSL® design. The rim of the Restoration® ADM Acetabular Shell has an anatomic cut-out to prevent conflict with the ilio-psoas muscle.

The Restoration® ADM X3® Acetabular Insert is composed of Stryker Orthopaedics sequentially annealed UHMWPE, X3®. The ID is compatible with a 28 mm Stryker femoral bearing head only. *The Restoration® ADM Acetabular Shell is **not intended for use** with the **Stryker LFIT™ Anatomic CoCr femoral bearing head larger than 28mm**.

The Restoration® ADM X3® Acetabular Shell is available in left and right configurations ranging in sizes 46 mm – 64 mm OD which are coupled with the polyethylene inserts ranging in sizes 40 mm - 58 mm OD. There is a 6 mm difference between cups and inserts and inserts are available in 0 degrees only.

The catalog numbers for the Restoration® ADM Acetabular Shell, permissible according to this study protocol are in the following format, where 'XXX' varies by size:

1235-2-XX1 (Right)

1235-2-XX2 (Left)

The catalog numbers for the Restoration® ADM X3® Acetabular Insert, permissible according to this study protocol are in the following format, where 'XX' varies by size:

1236-2-8XX

Table 2. Restoration® ADM X3® Acetabular System Shell/Insert Thickness/Head Compatibility

Restoration® ADM Shell (OD/mm)	Restoration® ADM X3® Insert (OD/mm)	Insert Thickness (mm)	Femoral Head Diameter (mm)
46	40	5.9	28
48	42	6.9	28
50	44	7.9	28
52	46	8.9	28
54	48	9.9	28
56	50	10.9	28
58	52	11.9	28
60	54	12.9	28
62	56	13.9	28
64	58	14.9	28

The patented[b] sequential irradiation and annealing manufacturing process for X3® offers increased wear resistance and virtually eliminates free radicals[c] while preserving mechanical

[b] U.S. Patent # 6,174,934 6,372,814 6,664,308 6,818,020 7,517,919

[c] X3 UHMWPE virtually eliminates free radicals, as measured by Electron Spin Resonance (ESR). A very low (noise level, near instrument detection limit) concentration of residual free radicals was detected in the X3 UHMWPE. A 99% reduction of free radicals ($14 \pm 2 \times 10^{14}$ spins/gram versus $1550 \pm 32 \times 10^{14}$ spins/gram) was found when compared to N2Vac gamma sterilized UHMWPE.

properties[d,e,f,g]. X3® is irradiated by 3 MRads gamma radiation and annealed (heated below melting temperature) three times for a total cumulative dose of 9 MRads.

The Accolade® II Hip Stem will be available in 12 sizes ranging from size 0 through 11. Stem length will range from 93 mm to 126 mm in 3 mm increments. The neck lengths of the Accolade® II Hip Stem range from 27 mm to 40 mm and are proportional relative to the different body geometry. Additionally, the necks are available in two angles (127° and 132°) that provide dual offsets.

For subjects implanted with the Accolade® II Hip Stem, the following catalog numbers are permissible according to this study protocol and are in the following format, where 'XXXX' varies by size:

6720-XXXX
6721-XXXX

6.2 Device Retrieval Process

Stryker Orthopaedics will retrieve any Restoration® ADM X3® Acetabular System components and the Accolade® II Hip Stem (when applicable) and/or adjacent tissues for analysis to help characterize potential device-related complications. In the event that any portion of the Restoration® ADM X3® Acetabular System or the Accolade® II Hip Stem is removed from a study subject, the procedure outlined in the Retrieval Analysis Protocol (Appendix B) should be followed. In addition:

[d] X3 UHMWPE maintains mechanical properties after accelerated oxidative aging. No statistical difference was found for Tensile Yield Strength, Ultimate Tensile Strength and Elongation as measured per ASTM D638 before and after exposure to ASTM F2003 accelerated aging (5 Atmospheres (ATM) of oxygen at 70ºC for 14 days). Tensile Yield Strength was 23.5 ± 0.3 MPa and 23.6 ± 0.2 MPa, Ultimate Tensile Strength was 56.7 ± 2.1 MPa and 56.3 ± 2.3 MPa and Elongation was 267 ± 7% and 266 ± 9% before and after accelerated oxidative aging, respectively.

[e] X3 UHMWPE resists the effects of oxidation. No statistical difference was found for Tensile Yield Strength, Ultimate Tensile Strength, Elongation, Crystallinity and Density as measured per ASTM D638, D3417 and D1505 before and after ASTM F2003 accelerated aging (5 ATM of oxygen at 70°C for 14 days). Tensile Yield Strength was 23.5 ± 0.3 MPa and 23.6 ± 0.2 MPa, Ultimate Tensile Strength was 56.7 ± 2.1 MPa and 56.3 ± 2.3 MPa, Elongation was 267 ± 7% and 266 ± 9%, Crystallinity was 61.7 ± 0.6% and 61.0 ± 0.5%, and Density was 939.2 ± 0.1 kg/m3 and 939.2 ± 0.2 kg/m3 before and after accelerated oxidative aging, respectively.

[f] "Improved Strength of Cross-linked UHMWPE Without Compromising Oxidation/Fatigue Resistance and Wear", Yau SS; Wang A, Lovell T. 2007 Combined ORS Poster #496.

[g] "Wear, oxidation and mechanical properties of a sequentially irradiated and annealed UHMWPE in total joint replacement", A.Wang, H.Zeng, S-S Yau, A. Essner, M. Manley and J. Dumbleton, Journal of Physics, D:Appl: Phys 39 (2006).

1. When revision of a study subject is scheduled, the study coordinator (SC) should contact the Clinical Study Manager (CSM) or Clinical Study Associate (CSA) assigned to the project, as soon as possible.
2. The CSM or CSA 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 B.
4. The SC, an identified field representative or the CSM/CSA will complete a Product Experience Report (PER).
5. If not completed by the CSM or CSA, the PER should be faxed to Stryker Product Surveillance at 201-831-6775, as well as to Stryker Clinical Research at 201-831-6454.
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. The CSM or CSA 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 will be screened to determine if they meet the inclusion/exclusion criteria. If the patient is a candidate, the investigator will propose participation in the study to the patient, according to GCP guidelines. Patients must sign an IRB/EC approved Informed Patient Consent Form prior to participating in any study related activities. Consent must be obtained within 4 months prior to surgery.

Once the patient has been consented, preoperative data will be collected including: demographics, medical history, HHS, SF-12, LEAS, EQ-5D, AP pelvis, AP femur and lateral radiographs.

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.

7.2 Surgery

Surgical details will be collected from the operative notes and at the time of surgery.

7.3 6-week Visit

During the 6-week visit (± 3 weeks), the following evaluations will be collected: HHS, SF-12, LEAS, EQ-5D, AP pelvis, AP femur and lateral radiographs.

7.4 Annual Follow-up Visits

Clinical data will be collected via office visit by the investigator at the following annual postoperative intervals: 1-year, 2-year, 3-year, 4-year and 5-year. Tools for postoperative evaluation will be the HHS, AP pelvis, AP femur and lateral radiographs. Radiographs will also be obtained at 1 year and then annually to 5 years postoperatively.

Patient outcomes data will also be collected with the required SF-12, LEAS, and EQ-5D patient questionnaires at each annual visit at the 1-year through 5-year follow-up visits.

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.

The initial phase of the study will continue for 5 years after surgery and include collection of the previously described radiographs, HHS, SF-12, LEAS and EQ-5D patient questionnaires. In the second phase of the study, all subjects will complete a brief Follow-up Questionnaire annually at the 6-year, 7-year, 8-year, 9-year and 10-year follow-up intervals. This form may be completed by the SC during a subject telephone interview, or by the subject either at home or during a clinic visit. The questionnaire will be used to obtain the following information, at a minimum:

- Subject satisfaction with the hip replacement
- Presence of any pain in the study hip
- Any surgeries performed on the study hip
- Any dislocations in the study hip

The questionnaire will also provide information on any revisions and enable calculation of the Kaplan-Meier Survival Curve necessary to meet the primary endpoint of the study.

Additionally, at investigational sites that choose to continue collecting clinical and radiographic data during the second phase of the study, subjects will be evaluated again at 7 and 10 years after surgery.

8 Adverse Events

8.1 Reporting of Adverse Events

The AE reporting requirements for this study are as follows:

- All AEs that meet the definition of serious, excluding elective procedures
- All AEs related to the operative site, regardless of seriousness

Elective procedures meeting the definition of an SAE do not need to be reported as AEs according to this study protocol. Examples of such elective procedures include, but **are not limited to**, the following commonly seen events:

- Contralateral THR
- Total Knee Replacement
- Rotator Cuff Surgery
- Cataract Surgery

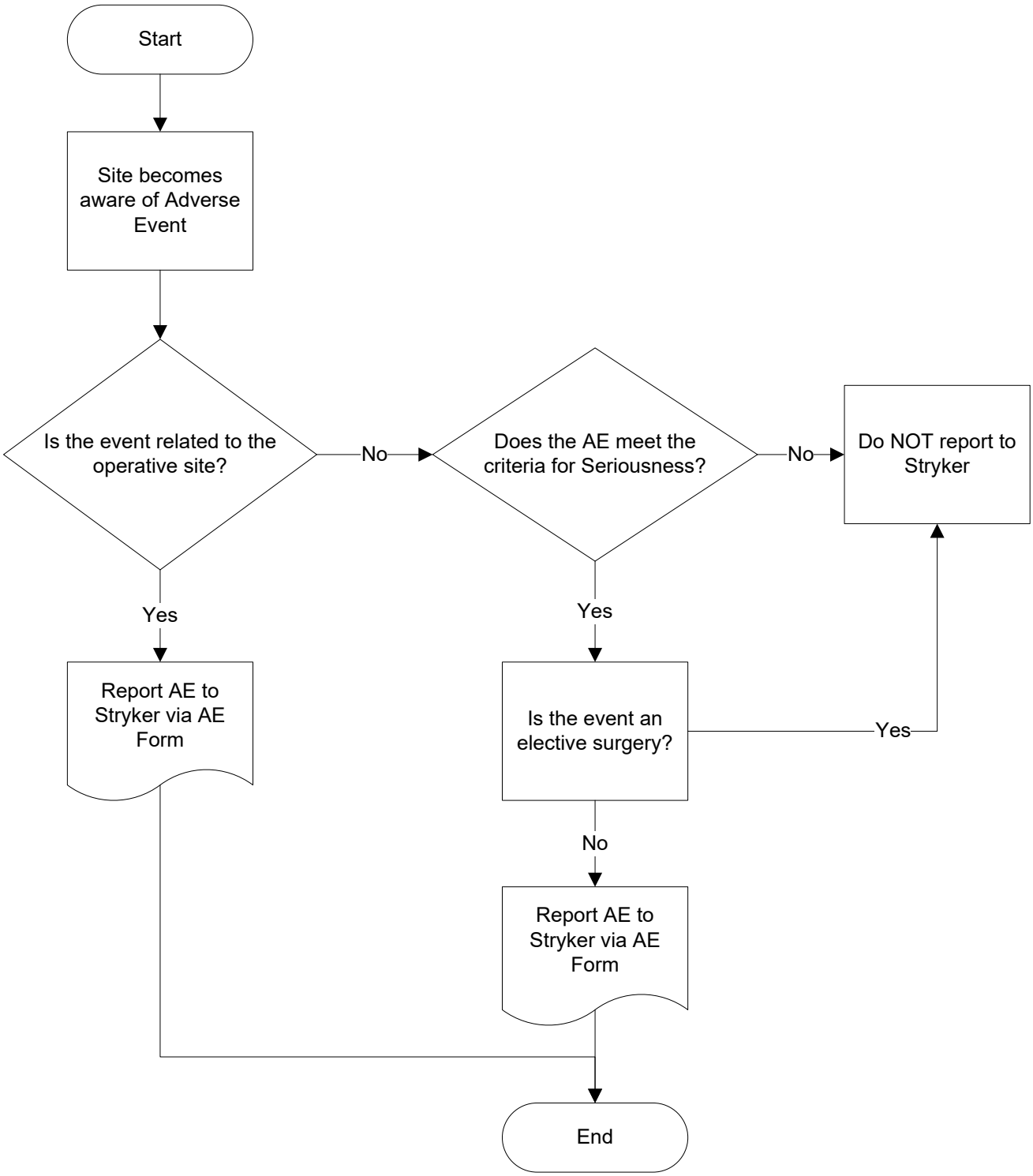
Such events will not be captured on the AE electronic Case Report Form (eCRF) but rather will be captured on the Postoperative Functional Evaluation at the 6-week, 1-year, 2-year, 3-year, 4-year and 5-year time points. Additional events of this nature will be captured on the 7-year and 10-year functional evaluations if the investigator chooses to bring subjects in for these optional visits. On these functional evaluations, investigators and SCs will be prompted to question subjects as to whether they have seen a doctor for any reason, been hospitalized for any reason or have a current impediment to their function.

Additionally, SCs will be responsible for following up with the subjects regarding any questionable responses received on the Follow-up Questionnaire administered in postoperative years 6 through 10. 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, as required.

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

Figure 4. 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, excluding elective procedures, as well as all AEs related to the operative site should be reported.

Adverse Event

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

Elective procedures meeting the definition of an SAE do not need to be reported as AEs according to this study protocol.

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 adverse event should be reported to the study sponsor (CSM or CSA) either by telephone/fax/email within 24 hours of the site's 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 hip or a revision of any study hip components.

An AE eCRF must be completed by the investigator within 24 hours. If a SAE occurs, the de-identified source documentation must be uploaded to the Subject Binder of Stryker's Electronic Data Capture (EDC) system, NetRegulus, 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 Product Experience Report (PER) is required.

It is recommended that all other reportable adverse events are reported on eCRFs and submitted to Stryker within 2 weeks.

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 requirements. Copies of each report and documentation of EC/IRB notification and receipt will 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.

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 femoral head dislocation for any reason at 10 years postoperative.

9.1.2 Secondary Efficacy Parameters

The secondary efficacy parameters are:

- HHS at each visit, as applicable
- SF-12 at each visit, as applicable
- LEAS at each visit, as applicable
- EQ-5D at each visit, as applicable
- Follow-up Questionnaire annually in postoperative years 6-10

9.1.3 Primary Efficacy Hypothesis

The null hypothesis, H_0, is that the success rate, defined as absence of postoperative femoral head dislocation, at 10 years postoperative is less than δ. The alternative hypothesis, H_a, is that the success rate at 10 years postoperative is greater than or equal to δ. When δ = 93.5%, the hypothesis is a test for non-inferiority. When δ=97%, the hypothesis is a test for superiority.

H_0: $p < \delta$

H_a: $p \geq \delta$

9.1.4 Primary Efficacy Analysis

A case success is defined as no incidence of postoperative femoral head dislocation within 10 years. A 90% confidence interval of the success rate will be computed at 10 years postoperative. If the lower bound of this confidence interval is greater than 93.5%, the non-inferiority hypothesis will be supported. If the lower bound of this confidence interval is above 97%, the superiority hypothesis will be supported. The Kaplan-Meier survival curve of femoral head dislocation for any reason will also be displayed using SAS/PROC LIFETEST.

9.1.5 Secondary Efficacy Analysis

A two-sided 0.05 alpha level will be used.

A paired t-test will evaluate the changes in clinical outcomes (HHS, SF-12 and LEAS) preoperative to 10 years postoperative within the Restoration® ADM X3® Acetabular System group, when data is available. In addition, the mean scores (HHS, SF-12 and LEAS) over time will be tabulated, with standard deviation and 95% confidence intervals presented, if applicable.

9.2 Safety Parameters

9.2.1 Safety Parameters

Safety parameters will include

- All AEs reported
- Rate of psoas impingement
- Rate of associated groin pain (derived from the 'Operative Site – Other' field on the AE form)

- Radiographic stability at each postoperative visit
- Revision or removal of any study component
- Revision or removal of the Restoration® ADM Acetabular Shell and X3® Acetabular Insert

9.2.2 Safety Analysis

All AEs will be listed, tabulated and summarized by event, number and percent of cases/subjects. AE rates and 95% confidence intervals will be presented.

For categorical variables, such as radiographic stability, the number and percent in each category will be presented.

The Kaplan-Meier survival curve of revision/removal of any study component and the Restoration® ADM Acetabular Shell and X3® Acetabular Insert will also be displayed.

9.3 Missing Data

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

9.4 Statistical Methodology

9.4.1 Data Summary

The following is a detailed proposal of statistical analyses planned for data collected during the study.

Descriptive statistics will be computed for all preoperative conditions and demographic parameters. That is, for continuous data (e.g. HHS), the N, mean, median, standard deviation, minimum and maximum will be computed. For categorical data (e.g. gender), the frequency and percentage will be computed.

Descriptive statistics and statistical comparisons for important demographic, efficacy and safety variables will be provided in tables.

A survival analysis will be performed.

9.4.2 Sample Size Calculation

A literature review shows that at 10 years of follow-up there is an approximate 97% success rate using postoperative femoral head dislocation as the defining factor. Using a base success rate of 97% from the literature and a delta of 3.5%, it was calculated that 274 total cases would be needed to prove non-inferiority with 95% confidence. With a minimum of 274 cases analyzed, the primary hypothesis of the study will be met if the lower bound of the one-sided 95% confidence interval for the 10-year success rate is greater than 93.5%. By factoring in a 20% lost to follow-up rate within a 10-year period, the required enrollment increases to 343 cases. A total of 350 cases will be enrolled into the study.

9.4.3 Interim Analyses and early Stopping Considerations

No interim analysis is planned.

9.4.4 Efficacy Patient Populations

9.4.4.1 Efficacy

Per protocol population:

The study population for analysis will include all subjects who receive the Restoration® ADM Acetabular Shell and Restoration® ADM X3® Acetabular Insert and have the primary efficacy variable measurements available. This does not include cases censored from analysis for a reason that may have a significant impact on outcome.

The primary efficacy analysis will be based on the per protocol population.

9.4.4.2 Safety

Safety Population:

The safety population will include all non-censored subjects who received the Restoration® ADM Acetabular Shell and Restoration® ADM X3® Acetabular Insert.

9.4.4.3 Survival Analysis

Modified intent to treat population:

Subjects enrolled in the study who received the Restoration® ADM Acetabular Shell and Restoration® ADM X3® Acetabular Insert will be included in the survival analysis.

9.4.4.4 Censored Cases

In the event that a protocol deviation occurs which could affect subject outcome, the data for the affected subject will be censored from the Efficacy and Safety Subejct Populations. All cases that fall into this category will be reported separately.

10 Study Procedures

10.1 Subject Recruitment and Screening

Patients will be recruited at the study centers during preoperative visits through normal referral patterns. All patients recruited for this study will 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.

10.2 Patient Informed Consent and Guidelines

All patients for this study will be provided an Informed Patient Consent Form describing this study and providing sufficient information for them to make an informed decision about their participation. The Informed Patient Consent Form must contain all elements required by the FDA under 21 CFR Part 50, in addition to any other elements required by state, local and institutional policies. For international sites, the applicable country regulations are required. See Appendix E for a copy of the Model Informed Patient Consent. This will be submitted with the protocol for review and approval by the IRB/EC for the study. All patients must provide written consent after having had adequate time to consider their participation in the study. The formal consent of a patient, using the IRB/EC approved Informed Patient Consent Form, must be obtained before that patient is submitted to any protocol related procedures that are not part of normal care. Written documentation of consent must be provided on the Informed Patient Consent Form's signature page in addition to a note in the patient medical records indicating the date that consent was obtained. The investigator-designated research professional obtaining the consent must also sign this Informed Patient Consent Form. The patient or his/her legal representative should receive a signed copy of the Informed Patient Consent Form, according to GCP guidelines.

The procedure for obtaining informed consent is outlined below:

- Use a current IRB/EC approved copy of the Informed Patient Consent Form.

- Review thoroughly with the patient 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 will be notified by the center that he/she is no longer in the study and a Study Termination eCRF will be completed.

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

Termination Reason	**Date of Termination**
Death	Date of death
Investigative center termination	Date of study close-out visit
Lost to follow-up	Date Stryker termination approval given
Voluntary withdrawal	Date subject notified center of withdrawal
Revision/removal of study device	Date of revision/removal procedure
Study device not implanted	Date of surgery
Surgery not performed	Date Stryker termination approval given

At the time of study surgery it is required that the following components are implanted for each treatment group:

Restoration® ADM X3® System with any compatible Stryker Stem:

- Restoration® ADM Acetabular Shell
- Restoration® ADM X3® Acetabular Insert

- 28 mm Stryker femoral head (except for the LFIT™ Anatomic CoCr femoral bearing head)
- Compatible Stryker femoral stem (with a minimum of 100 Accolade® II Hip Stems)

Revision or removal of the Restoration® ADM X3® Acetabular System (acetabular shell and insert) constitutes a failure and study termination for the subject.

If femoral stem or femoral head revision is required during the study, the event is considered a reoperation and does not constitute a failure or study termination.

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

In the event a subject does not have surgery, Stryker should be contacted to discuss if/when the surgery will be rescheduled. If the surgery is rescheduled more than 4 months from the date of 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 Electronic Data Capture (EDC) system, NetRegulus. 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 will comply with the 2002 HIPAA privacy rule. As such, Stryker will only collect that information which is necessary to support the objectives of the clinical study. Stryker will take precautions to ensure that data received is as de-identified as possible. In the case that some identified information is received, Stryker will ensure that any identifying information is not reported. Study subjects will authorize Stryker to use their health information in support of the clinical study during the informed consent process. Should a subject choose to withdraw authorization, Stryker may use data collected prior to the withdrawal of authorization in order to maintain data integrity.

11.3 Source Documents

Source data is 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 follow-up visits must be documented in the subject's chart. This includes ROM 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, will be comparing the eCRFs against source documents for adequacy. The monitors will seek to draw a reference between each data point on the CRF 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.

For specific instructions on eCRF completion, please consult the Guide to Electronic Case Report Forms provided under separate cover. eCRFs should 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 data entry of the eCRFS, a data clarification request (DCR) will be sent to the center via the EDC system. Queries should be answered in a clear and comprehensible manner. If the clarification requires a change to data captured on an eCRF, Stryker will modify the eCRF accordingly. The investigative center will be required to reapply their electronic signature to the modified eCRF. Modified eCRFs need not be printed and included in conjunction to answered DCRs.

11.6 Protocol Deviations

Any deviation from this protocol will be reported to Stryker as well as to the EC/IRB according to their reporting procedures. Protocol Deviations for this study include, but are not limited to, the following:

- 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
    - One or more required eCRFs/radiographs not done
    - Evaluations occurred outside of protocol specified time window
    - Un-evaluable radiographs
    - Missed visit

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 THR procedure.

12.2 Potential Risk

The study involves the routine assessment of a primary THR procedure. The Restoration® ADM X3® Acetabular System and Accolade® II Hip Stem have been cleared for use by the FDA and will be used according to their labeling, included in Appendix C. 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 THR 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 THR 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, UHMWPE and/or ceramic. 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 hip 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.

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

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

Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular 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, girdlestone or amputation of the limb.

12.3 *Expected Complications and Rates of Occurrences*

Complications associated with THA procedures, such as those performed with the Restoration® ADM X3® Acetabular System, have been reported. These include the potential for: injury to the hip's neurovascular structures, loosening of the components, malseating of the acetabular liner, heterotopic bone formation, infection, deep vein thrombosis, pulmonary embolism, metal sensitivity reactions, intraoperative or postoperative fracture of the femur or acetabulum, and the need for re-operation, revision, arthrodesis of the involved joint, girdlestone or amputation of the limb. The safety objective will compare the complication rates of the Restoration® ADM X3® Acetabular System to published rates.

12.4 Protection Against Risks

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

12.5 Potential Benefits to the Subject

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

Additionally at pre-determined study visit intervals, Stryker may reimburse subjects with a modest stipend for protocol-required data collection. This stipend system must be approved by the Institution's IRB prior to implementation and will be based upon individual IRB approval from each site.

The monetary value of the gifts to the subjects is modest and should not unduly coerce them to participate in the study.

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

- An area where they can review study data
- Subject case books

- Patient charts pulled at the center
- Regulatory documents
- Time to meet 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 will permit study-related monitoring, audits, and inspections by the EC/IRB, Stryker and/or government regulatory bodies of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data). The investigator will ensure the capability for inspections of applicable study-related facilities.

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 will be submitted to a properly constituted independent EC/IRB for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to Stryker before commencement of this study. The investigator may be asked to provide a list of EC/IRB members and their affiliates to Stryker, if available.

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

Patient Consent Form must be signed by the patient or legally acceptable surrogate and the investigator-designated research professional obtaining the consent.

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. After receipt of the completed data forms, the physician must submit either evidence of coverage denial (e.g. explanation of benefits) or a letter explaining that the subject does not have insurance. Other visits, procedures and assessments done other than those specified in the protocol will not be reimbursed. Reimbursement may be provided under the following conditions:

- Study subjects lose insurance coverage after enrollment into the study
- An insurance carrier refuses to pay for a follow-up visit and/or radiographs
- An insurance carrier refuses to provide a subject referral to see the investigator for follow-up

Additionally at pre-determined study visit intervals, Stryker may reimburse subjects with a modest stipend for protocol-required data collection. This stipend system must be approved by the Institution's IRB prior to implementation and will be based upon individual IRB approval from each site.

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. Additional publication proposals may 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. 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.

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Appendix A

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 implant-bone interface.

- AP pelvis
- AP femur
- Lateral femur

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 hips 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. 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 Pelvis

If the subject is bilateral, two copies of the AP pelvis radiograph are needed.

A. Standard technique
    a. 100 cm tube to film distance.
    b. The subject should be supine with his/her sacrum flat against the table and legs in full extension, internally rotated 15°, compensating for the normal anteversion of the femoral neck.
    c. The x-ray beam should be directed perpendicular to the film cassette and must be centered on the pubic ramus.

d. The iliac bones, sacrum, pubis, ischium, femoral heads, femoral necks and both the greater and lesser trochanter must be visible on film as shown below.

Refer to Figure 1 for an acceptable AP pelvis radiograph.

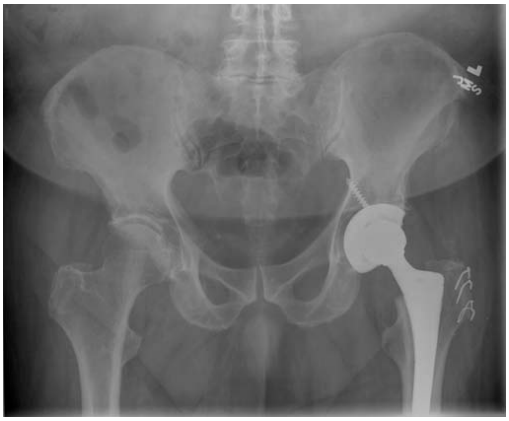

Figure 1. AP Pelvis View – <u>Acceptable</u>

Refer to Figure 2 for AP subject positioning.

Figure 2. AP Positioning

AP Femur

A. Standard technique.
   a. 100 cm tube to film distance.
   b. The patient should be supine with their sacrum flat against the table and legs should be in full extension and internally rotated with toes touching.
   c. The film cassette should be placed immediately below the table, parallel to the subject's frontal plane.
   d. The x-ray beam should be directed perpendicular to the film cassette and should be centered toward the center of the involved hip.

e. The distal tip of the femoral stem, femoral head and neck, greater and lesser trochanter, and the acetabulum must be included in this x-ray.

Refer to Figure 2 for AP pelvis and AP femur subject positioning.

Lateral Femur[ii, iii]

A. Standard technique

a. The subject should be supine with the involved leg flat against the table.
b. The knee of the involved leg should be flexed 90° and the thigh drawn up to at least a 45° angle.
c. The x-ray beam should be directed over the lesser trochanter, perpendicular to the proximal femur.
d. The entire hip joint must be visible.

Refer to Figure 3 for an acceptable lateral radiograph.

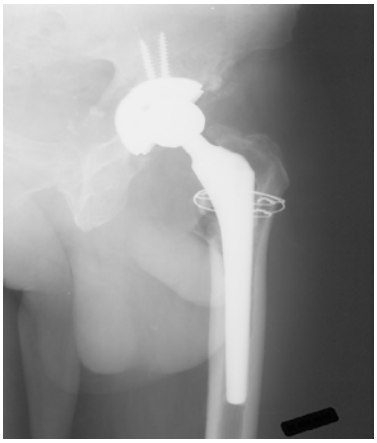

Figure 3. Lateral View – <u>Acceptable</u>

Refer to Figure 4 for subject positioning.

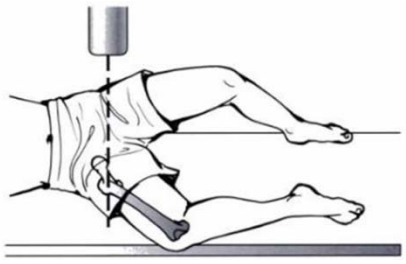

Figure 4. Lateral Positioning

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Appendix B

Retrieved Implant Analysis Protocol

RETRIEVED IMPLANT ANALYSIS PROTOCOL

Restoration® Anatomic Dual Mobility (ADM) X3® Acetabular System
With Long Term Data Collection for the Accolade® II Hip Stem

PURPOSE:

To evaluate retrieved Stryker Orthopaedics Restoration® ADM X3® Acetabular System components, the Accolade® II Hip Stem, 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 Restoration® ADM X3® Study [510(k) clearance # K093644 - December 18, 2009] will be asked to comply with the Retrieved Implant Analysis Protocol. Whenever possible, subjects who undergo revision/removal of the acetabular cup or acetabular insert component of the Stryker Orthopaedics Restoration® ADM X3® Acetabular System or revision of the Accolade® II Femoral Stem 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 for implant analysis is attached to this protocol as Appendix E.

This study protocol will comply with the 2002 privacy rule of the Health Insurance Portability and Accountability Act (HIPAA). 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 for implant analysis. 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 Restoration® ADM X3® Acetabular System, Accolade® II Hip Stem 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.

A sample Specimen Information Form is attached to this protocol. Specimens should be carefully sealed and mailed by express mail to:

Stryker Orthopaedics
Product Surveillance
325 Corporate Drive
Mahwah, NJ 07430

Recommendations for packing and shipping explants are attached to this protocol.

C. Specimen Evaluation:

Devices will be evaluated with particular attention to documenting potential device-related complications. Explanted devices will be viewed with a dissecting microscope and examined for evidence of wear, deformation, corrosion or fracture. Modular interfaces will be similarly evaluated for evidence of corrosion or wear. Tissue samples will be decalcified if necessary, embedded, sectioned and the resulting microscope slides evaluated by a board certified pathologist with expertise in orthopedic pathology and biomaterials. Histologic evaluation will focus on the presence or absence of visible

wear debris particles, the biologic response to debris and any other relevant findings (e.g. evidence of infection, unusual inflammatory or foreign body reaction, etc.).

Implant Retrieval Study
Specimen Information Form

1. Subject Initials: _____ ID #: 70 - __ __ - __ __ __ __

Brief Subject History:

2. Hip (circle one): Left Right

3. Primary diagnosis made prior to total hip surgery: _____

4. Radiographic findings prior to total hip surgery: _____

5. Date of implantation of this device: ____ / ____ / ____

6. Name of implanting physician (study investigator): _____

7. Relevant postoperative clinical and radiographic findings: _____
   _____
   _____
   _____

Recent Subject History:

8. Describe reason for explant, including any patient symptoms/conditions experienced prior to the explant surgery: _____
   _____
   _____

9. Radiographic findings prior to explant surgery: _____
   _____

10. Date of explant surgery: ____ / ____ / ____

11. Name of explant surgeon: _____

12. Location of explant surgery: _____

13. Surgical findings during explant surgery: _____
    _____

14. Were there any difficulties encountered while explanting the device(s) that may have damaged any of the explanted components? (circle one): Yes / No
    If Yes, describe what occurred: _____
    _____
    _____

15. Other relevant medical history: _____
    _____
    _____

16. Name and Address for Interpretive Report: _____

_____

Please enclose this form and relevant attachments with the specimen(s).

Please send a copy of this form to the Restoration® ADM X3® Study CSM, identified on the Stryker Orthopaedics Contact Sheet at the following address: Clinical Research Department, Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ 07430

Recommendations for Packing and Shipping Explants
To Stryker Orthopaedics

Please contact the Restoration® ADM X3® 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
Product Surveillance
325 Corporate Drive
Mahwah, NJ 07430

RESULTS

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

I acknowledge this retrieval analysis protocol and will enforce it once IRB approval is obtained.

_____ _____

Investigator Signature Date

Appendix C

Product Labeling

stryker
Howmedica
OSTEONICS

TOTAL HIP JOINT REPLACEMENT PROSTHESES FOR CEMENTLESS & CEMENTED APPLICATIONS

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

OR

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203 Bd de la Grande Delle – BP 8
14201 Hérouville-Saint-Clair Cedex
France

EC REP

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

Telephone #: +1 201-831-5000

CE 0086

96E112 Rev. E

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

TOTAL HIP JOINT REPLACEMENT
PROSTHESES FOR CEMENTLESS & CEMENTED APPLICATIONS

ATTENTION OPERATING SURGEON

The advancement of partial and total hip replacement has provided the surgeon with a means of restoring mobility and reducing pain with the use of implanted prosthetic devices. While these devices have proven to be largely successful in obtaining these goals, they are manufactured from metal, plastic, or other biomaterials. Any partial or total hip replacement system, therefore, cannot be expected to withstand the same activity and loads of normal healthy bone and the system will not be as strong, reliable or durable as a natural human hip joint.

In using total joint implants, the surgeon should be aware of the following:

A. The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the implant. Total joint prostheses require careful seating and adequate bone support.

B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:

1. **The patient's weight.** The heavier the patient, the greater the load on the prosthesis. As the loads on the prosthesis increase, the chance a patient will suffer adverse reactions, such as failure of fixation, loosening, fracture and dislocation of the device and can lead to a decreased service life. The effect of these loads will be accentuated when a small sized prosthesis is used in larger patients. As obesity is a clinical diagnosis, we leave it to the surgeon to make the diagnosis based on his/her own clinical judgment. However, the World Health Organization (WHO) defines "overweight" as a BMI equal to or more than 25, and "obesity" as a BMI equal to or more than 30.
2. **The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting, or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activity over the years can also accentuate the normal wear process that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have, and should be disabused of, unrealistic functional expectations. (See **PRECAUTIONS** section for more information).
3. **A condition of senility, mental illness, chemical dependence or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

DESCRIPTION
Stryker Orthopaedics manufactures a wide variety of reconstructive total hip systems to satisfy anatomical requirements and surgeon/patient needs. Please refer to the applicable, Surgical Protocol for further product specific detail.

Stems
A wide range of femoral stems are available, monolithic or modular with associated necks, in straight or anatomic designs; collared or collarless configurations; with and without coatings; and with or without preformed cement mantles manufactured from polymethylmethacrylate (PMMA). The materials used to manufacture these stems are certified to ASTM and/or ISO Standards:

Material:	**ASTM Standard / ISO Standard**
VITALLIUM Alloy	
Cast	F75 / 5832-4
Forged	F799
Wrought	F1537 / 5832-12
Gas Atomized Dispersion Strengthened (GADS)	F1537
Forged Titanium Alloy (Ti 6Al-4V)	F136 / 5832-3
TMZF (Ti 12Mo-6Zr-2Fe)	F1813
ORTHINOX	F1586 / 5832-9
Stainless Steel	F138 / 5832-1

See the surgical technique for the components that are compatible for the specific hip system.

Acetabular Cups
Acetabular cups are available in a wide range of outer diameter sizes and several inner diameters. Cup styles include one-piece all polyethylene (some of which are Duration treated) or metal; one-piece metal backed/polyethylene (some of which are Duration treated); one-piece Carbon Fibre Reinforced Poly Ether Ether Ketone (CFR PEEK) ***; and two-piece cups consisting of a metal shell and a polyethylene, ceramic*, or Carbon Fibre PEEK*** insert. Some acetabular cups are available with polymethylmethacrylate (PMMA) spacers.

Acetabular cups are manufactured in a range of outer diameters to satisfy various anatomical requirements and surgeon needs. The acetabular cups are available with and without holes and coatings.

Acetabular cups may be manufactured from Titanium alloy, cobalt chrome alloy, stainless steel, ceramic, UHMWPE or Carbon Fibre Reinforced Poly Ether Ether Ketone (CFR PEEK). The PEEK (Mitch PCR Cups) is ONLY compatible for use with ceramic** femoral heads and NOT femoral heads manufactured from metal alloys.*** These cups are manufactured from materials certified to ASTM and/or ISO Standards:

Material:	**ASTM Standard / ISO Standard**
VITALLIUM Alloy	
Cast	F75 / 5832-4
Forged	F799
Wrought	F1537 / 5832-12
Gas Atomized Dispersion Strengthened (GADS)	F1537
Forged Titanium Alloy (Ti 6Al-4V)	F136 / 5832-3
ORTHINOX	F1586 / 5832-9
Stainless Steel	F138 / 5832-1
UHMWPE	F648/ 5834-2
PMMA	D788/ 8257-1

Surgical Mesh
Surgical Mesh is intended to be used to reinforce bone or tissue in any situation where additional strengthening and support is required due to poor bone/tissue quality.

Material:	ASTM Standard / ISO Standard
Cast VITALLIUM Alloy	F75 / 5832-4
Wrought VITALLIUM Alloy	F1537 / 5832-12
Titanium Alloy (Ti 6Al-4V)	F136 / 5832-3
Stainless Steel	F138 / 5832-1
Alumina* ($Al_2 O_3$)	F603 / 6474

Acetebular Inserts

The inserts are available with varying inner diameters to help accommodate the mating femoral head. The inserts used with the two-piece cups are designed with a snap lock mechanism to securely lock into the metal shell. The Ultra High Molecular Weight Polyethylene (UHMWPE) inserts and one-piece PE cups are manufactured from materials certified to ASTM Standard F648 and/or ISO 5834-2. These UHMWPE components may contain an x-ray location wire manufactured from wrought VITALLIUM Alloy certified to ASTM standard F1537, or from ORTHINOX Stainless Steel certified to ASTM F1586 / ISO 5832-9, or from titanium alloy (Ti 6Al-4V) certified to ASTM F136/ ISO 5832-3. The Alumina* inserts are manufactured from materials certified to ASTM Standard F603 / ISO 6474.

HOWMEDICA OSTEONICS inserts and acetabular cups made of polyethylene (UHMWPE) are compatible (except when specifically mentioned) with all HOWMEDICA OSTEONICS femoral heads of the same diameter.

Coatings

The coatings incorporated on the stems and metal shells consist of: sintered VITALLIUM Alloy beads, MADREPORIQUE Beads***, titanium plasma spray, a titanium bond layer overlaid with a layer of hydroxyapatite, or sintered VITALLIUM alloy beads overlaid with a layer of Peri-Apatite. These materials are certified to ASTM and/or ISO Standards:

Material:	ASTM Standard / ISO Standard
VITALLIUM Alloy Beads	F75 / 5832-4
Titanium Commercially Pure (CP)	F1580 / 5832-2
Hydroxyapatite (powder)	F1185
Peri-Apatite	F1185 (Chemical properties)

Heads

The femoral heads are available in a wide range of outside diameters to mate with varying acetabular components. The femoral neck length can be selected pre-operatively from a range of available neck lengths. These femoral heads are manufactured from materials certified to ASTM and/or ISO Standards:

Material:	ASTM Standard / ISO Standard
Forged VITALLIUM Alloy	F799
Cast VITALLIUM Alloy	F75 / 5832-4
ORTHINOX	F1586 / 5832-9
Stainless Steel	F138 / 5832-1
Ceramic** Femoral Heads	
Alumina** ($Al_2 O_3$)	F603 / 6474

A complete list of total hip reconstructive prostheses, trials, templates, accessories, instruments and surgical techniques can be found in the U.S. and International Howmedica Osteonics Corp.'s product catalogs.

Modular Neck

Material:	ASTM Standard / ISO Standard
Vitallium Alloy Forged	F799
Gas Atomized Dispersion Strengthened (GADS)	F1537

The ABG II Modular Neck must be firmly seated on the ABG II Modular Femoral Stem to prevent disassociation. Only ABG II Modular Necks may be used with ABG II Modular Stems. The neck cannot be reused after having been subjected to weight bearing loads in patients. The long ABG II Modular necks can only be used with stem sizes 3 to 8. The long necks cannot be used with stem sizes 1 and 2. The ABG II Modular Necks cannot be used with head offsets greater than +5mm.

Modular Stem

Material:	ASTM Standard / ISO Standard
TMZF (Ti 12Mo-6Zr-2Fe)	F1813

The ABG II Modular Stem comes with a plastic inserter that is prepackaged in the stem. This inserter is single-use and must be properly disposed according to hospital procedures immediately after removal from the stem. Ensure that no soft tissue or any other material has entered the stem taper after removing the inserter and trial neck and prior to implantation of the modular neck. ABG II Modular Stem sizes 1 and 2 can only be used with the short ABG II Modular Necks. Deviation from these specifications may affect the structural integrity of the neck/stem modular junction. Use contrary to these specifications will negate the responsibility for device performance.

Label Information

The product label provides information regarding specific material(s) from which the product is manufactured.

INDICATIONS

The indications for use for total hip and hemi hip arthroplasty include:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis (except the OSTEOLOCK HA Acetabular Cup and Peri-Apatite coated prostheses);
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional Indications for the Restoration ADM System:

1. dislocation risks

See constrained acetabular package insert (QIN 4357) for indications for constrained acetabular inserts.

The Peri-Apatite coated prostheses are indicated only for primary uncemented total hip arthroplasty for items 1, 3 & 5 above when offered for sale in the USA.

HIPSTAR Femoral Stems and RESTORATION ADM Cups are intended for cementless use only.

In the USA, when mated with a constrained acetabular liner the HIPSTAR Hip Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

CONTRAINDICATIONS

1. overt infection;
2. distant foci of infections (which may cause hematogenous spread to the implant site);
3. rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
4. skeletally immature patients; and
5. cases where there is a loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. osteoporosis;
3. metabolic disorders which may impair bone formation;
4. osteomalacia; and
5. obesity.

Additional conditions presenting increased risk of failure pertaining to the Surgical Mesh include:

1. Previous history of infections
2. Overt Infection
3. Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing
4. Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
5. Malignancy in the surgical area
6. Mental Physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen

WARNINGS

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in service life of the prosthetic implant. The surgeon must be thoroughly familiar with the surgical procedure, instruments, and implant characteristics, prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and condition of the prosthetic components, as well as the condition of the adjoining bone.

Cemented Application. Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips, bone cement fragments, and metallic debris) of the articular surfaces of the implant is necessary prior to closure.

For those stems containing an integral cement spacer, **DO NOT IMPACT** directly on the integral cement spacer.

Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device. Press-fit acetabular components require a precise operative technique and use of specified instruments. Adequate Acetabular preparation is important for the success of the procedure.

Hydroxylapatite coated implants are not intended for use with bone cement. Porous coated implants are generally intended for cementless use in primary applications where there is adequate bone stock. In revision procedures, porous coated implants are intended for cemented use only.

Acetabular Fixation. Care must be taken when determining and selecting the proper length of screws or spikes. Perforation of the pelvis with screws/spikes that are too long can rupture blood vessels causing the patient to hemorrhage. Screws/spikes are manufactured from materials to match that of the acetabular shells, and screw/cup materials should not be mixed. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Modular Acetabular Shell/Liner. Fixation devices, when used, should be fully seated to assure stable fixation of the shell, and to avoid interference with the liner component. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell. Debris may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

Ceramic* inserts are to be used exclusively with HOWMEDICA OSTEONICS Alumina Ceramic** Heads.

Modular Femoral Head

Femoral Head Compatibility

Howmedica Osteonics Corp. manufactures femoral heads with several tapers and diameters in both metal and ceramic**. Care must be taken to use stems and heads with the same taper angle and diameter. See product label for the specific taper information, such as angle and diameter.

Femoral head prostheses are indicated for use in cemented and cementless total hip arthroplasty, depending upon the indications of the acetabular and femoral stem components chosen.

The modular head component must be firmly seated on the femoral component to prevent disassociation. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head/neck component to the femoral stem could compromise a critical locking action of the taper socket joint. The head/neck component should be changed only when clinically necessary.

Complete cleaning of the male taper (complete removal of bone chips, bone cement fragments and any traces of body fluid) is necessary prior to placement of the femoral head to ensure stable fixation.

Howmedica Osteonics Corp. prohibits the use of other manufacturers' femoral heads on HOWMEDICA OSTEONICS' Femoral Stems; however, outside of the U.S., Finsbury Orthopaedics' femoral heads may be used with HOWMEDICA OSTEONICS' Femoral Stems.

22.2mm Femoral Head. Due to its small size, use of the 22.2mm femoral head and 22.2mm inner diameter acetabular insert may result in reduced range of motion which may result in an increased risk of dislocation and disassociation. This product should be used, subject to the medical judgment of the surgeon, when 22.2mm components are warranted.

Skirted Femoral Head. Heads with a high offset and skirted design may result in reduced range of motion which may result in an increased risk of dislocation and disassociation. This product should be used, subject to the medical judgment of the surgeon, when heads with a skirted design are warranted.

Based upon laboratory testing, the +8mm and larger modular heads are not recommended for use on all HOWMEDICA OSTEONICS Hip Stems. See additional labelling for the specific stems that are contraindicated for use with these heads.

See maximum femoral head offset warning on package label and HIPSTAR trunnion.

Ceramic** Heads

- HOWMEDICA OSTEONICS Ceramic** Femoral Heads are intended to mate only with HOWMEDICA OSTEONICS Femoral Stem Components labeled for use with ceramic** heads and with the correct taper angle and diameter. HOWMEDICA OSTEONICS Ceramic** Heads should not be used with other manufacturers' femoral stem components. HOWMEDICA OSTEONICS Ceramic** Femoral Heads should not be used in procedures where only the femoral head component of a total hip replacement is being revised.
- Do not impact (hammer) directly on the ceramic** head. HOWMEDICA OSTEONICS Ceramic** Heads should not be used if dropped or damaged during preparation.

Metal Components

Some of the alloys utilized to produce orthopaedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon.

Polyethylene Wear. As would be expected, wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to relatively early revision surgery to replace the worn prosthetic components.

PRECAUTIONS

Information for patients. The surgeon 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.

The surgeon must 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.

The surgeon must warn patients of surgical risks, and inform them of possible adverse effects. The surgeon must warn patients that the device does not replicate the flexibility, strength, reliability, or durability of 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.

Interaction with Magnetic Resonance Imaging

The EXETER and ABG II Modular Hip Stem Systems have not been evaluated for safety and compatibility in the MR environment. The EXETER and ABG II Modular Hip Systems have not been tested for heating or migration in the MR environment.

Instruments. Specialized instruments are available and must be used to help assure the accurate implantation of prosthetic components.

While rare, intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are more susceptible to fracture. Instruments must be examined for wear, or damage, prior to surgery.

Re-use. An implant must never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Handling. Handling of implants is important, particularly porous coated implants. Do not allow the porous coated surfaces to come in contact with cloth or other fibre releasing materials. The highly polished portion of the implant should not come in contact with hard surfaces.

(See **OTHER IMPORTANT INFORMATION** section for more information.)

ADVERSE EFFECTS

1. With all joint replacements, asymptomatic, localized progressive bone resorption (osteolysis) may occur around, or remote from, the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information).
2. Although rare, sensitivity/allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
3. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.
4. Dislocation and subluxation of implant components can result from improper positioning or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5. Implants can loosen or migrate due to trauma or loss of fixation.
6. Infection can lead to failure of the joint replacement.

7. Fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, and/or duration of service, singularly or in combination.
8. Fracture of the femur can occur while seating the femoral stem component into the prepared femoral canal.

Intraoperative and early postoperative complications can include:

1. femoral or acetabular perforation, or fracture;
2. femoral fracture while seating the device;
3. damage to blood vessels;
4. temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
5. undesirable shortening or lengthening of the limb;
6. traumatic arthrosis (joint disease caused by trauma) of the knee from intraoperative positioning of the extremity;
7. cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction, or death;
8. hematoma;
9. delayed wound healing; and
10. infection.

Late postoperative complications can include:

1. trochanteric avulsion (tearing away of soft tissue from the bone) as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
2. trochanteric nonunion due to inadequate reattachment and/or early weight bearing;
3. aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency;
4. femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
5. periarticular calcification or ossification, with or without impediment to joint mobility;
6. the following, singularly or in combination can lead to and/or cause decreased range of motion: improper selection or positioning of components, femoral impingement, and/or periarticular calcification; and
7. progressive bone resorption and osteolysis.

IMPORTANT PHYSICIAN INFORMATION

Bone Resorption and Osteolysis. Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal ions, UHMWPE, ceramics* and Carbon Fibre Reinforced PEEK***), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. It has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate from the synovial cavity and into the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated *in vitro* to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

Since osteolysis is frequently asymptomatic, the patient's normal periodic radiographic examination is a good way to detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of local lesions which are progressive may necessitate replacement of the prosthetic component(s).

OTHER IMPORTANT INFORMATION

A. Particular attention should be paid when handling those prostheses that have some type of coating, e.g., hydroxyapatite or beads. Contact between the coated surface and cloth or other fibre releasing materials should be avoided in order to minimize contamination of the coated surface with adherent materials. All implants where the coating has been damaged or contaminated should be discarded.

B. **Titanium Plasma Sprayed Devices**
The United States Food and Drug Administration (FDA) believes that reasonable assurance of the safety and effectiveness of components with Titanium Plasma Sprayed surfaces has not yet been established by long term (i.e., nine years and greater) studies. In bench testing, plasma sprayed porous coatings have shown lower mechanical strength and lower resistance to abrasion than sintered cobalt chromium alloy bead coatings or sintered titanium fibre mesh coatings. Clinically, loss of the titanium plasma sprayed coating could lead to compromise of function or failure of the device, necessitating revision. The FDA has mandated post market surveillance of these devices until such time as a nine year follow up is achieved. Patients receiving these devices should be monitored to insure that the plasma sprayed device is not failing earlier than reasonably expected due to metal debris, coating spalling or coating delamination. These conditions could result in significant incapacitation and require revision surgery. Short term (i.e., less than four years) clinical data have not identified any significant differences in the clinical failure rate between titanium plasma sprayed porous coated hip systems and hip systems with sintered porous coatings.

C. **Product Label.** See product label for information regarding the specific product referenced in this package insert.

HOW SUPPLIED
These components have been sterilized by gamma radiation or hydrogen peroxide. Refer to the package label for the specific sterilization method. The package of all sterile products should be examined prior to use for possible breaks in the sterile barrier.

- Do **NOT** resterilize.
- Take care to prevent contamination of any components.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is nonsterile.
- Discard ALL nonsterile or contaminated products.
- 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 in the USA restricts this device to sale by or on the order of a physician.

* Consult the TRIDENT Acetabular Component System IFU (QIN 4365) for indications, contraindications, warnings, and precautions on the TRIDENT Alumina ceramic insert.

** Consult the TRIDENT Acetabular Component System IFU (QIN 4350) for indications, contraindications, warnings, and precautions on the ceramic femoral heads.

*** Not available for sale in the USA.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademark(s) or service mark(s): Exeter, ABG, Duration, Hipstar, Howmedica, Madreporique, Mitch, Mitch PCR, Orthinox, Osteolock, Osteonics, Peri-Apatite, Restoration, Stryker, Stryker Orthopaedics, TMZF, Trident, V40, Vitallium, X3. All other trademarks are trademarks of their respective owners or holders.

BIOLOX® *delta* is a registered tradmark of CeramTec AG.

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		

stryker Howmedica OSTEONICS

Restoration® ADM and MDM™ Liner

Howmedica Osteonics Corp.
325 Corporate Drive
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A subsidiary of Stryker Corporation

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Telephone #: +1 201-831-5000

EC REP

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

CE 0086

QIN 4400 Rev B

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

Sterilized using Irradiation

Sterilized using Hydrogen Peroxide

Sterilized using Ethylene Oxide


Use by Date


Date of Manufacture


Legal Manufacturer

Authorized Representative in the European Community

Catalog Number

Batch Code

Serial Number

CONTENTS

Restoration ADM and MDM Liner

ATTENTION OPERATING SURGEON

The advancement of partial and total hip replacement has provided the surgeon with a means of restoring mobility and reducing pain with the use of implanted prosthetic devices. While these devices have proven to be largely successful in obtaining these goals, they are manufactured from metal, plastic, or other biomaterials. Any partial or total hip replacement system, therefore, cannot be expected to withstand the same activity and loads of normal healthy bone.
The system will not be as strong, reliable or durable as a natural human hip joint and does not have an infinite lifetime. The surgeon must warn patients about device limitations.

In using total joint implants, the surgeon should be aware of the following:

A. The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the implant. Total joint prostheses require careful seating and adequate bone support.

B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight. The heavier the patient, the greater the load on the prosthesis. As the loads on the prosthesis increase, the chance a patient will suffer adverse reactions, such as failure of fixation, loosening, fracture and dislocation of the device and can lead to a decreased service life. The effect of these loads will be accentuated when a small sized prosthesis is used in larger patients. As obesity is a clinical diagnosis, we leave it to the surgeon to make the diagnosis based on his/her own clinical judgment. However, the World Health Organization (WHO) defines "overweight" as a BMI equal to or more than 25, and "obesity" as a BMI equal to or more than 30.
2. The patient's occupation or activity. If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting, or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activity over the years can also accentuate the normal wear process that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have, and should be disabused of, unrealistic functional expectations. (See PRECAUTIONS section for more information).
3. A condition of senility, mental illness, chemical dependence or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

DESCRIPTION

Stryker Orthopaedics manufactures a wide variety of reconstructive total hip systems to help satisfy anatomical requirements and surgeon/patient needs. Please refer to the applicable, Surgical Protocol for further product specific detail.

ADM Acetabular Cups

Acetabular cups are available in a range of outer diameter sizes. The Restoration ADM system is a two-piece system consisting of a metal HA coated shell and a polyethylene insert.

The outer acetabular cup is manufactured from cobalt chrome alloy and coated with CP Ti, and hydroxylapatite. The cobalt chrome cups are manufactured from materials certified to ASTM Standard ASTM F1537.

MDM Liner
The MDM (Modular Dual Mobility) Liner is a highly polished modular liner with a Trident locking mechanism. This will allow for compatibility with acetabular cups containing the same locking mechanism. Refer to the surgical protocol for outer acetabular shell/ dual mobility insert compatibility. The Restoration ADM Inserts articulate within the MDM Liner. The MDM Liner is manufactured from cobalt chrome alloy certified to ASTM Standard ASTM F1537.

Polyethylene Insert
The inner acetabular polyethylene inserts are available with an inner diameter that accommodates the mating femoral head.
The inserts used with the cups are designed to move freely in the cup. The Ultra High Molecular Weight Polyethylene (UHMWPE) inserts are manufactured from materials certified to ASTM Standard F648 and/ or ISO 5834-2.

HOWMEDICA OSTEONICS Inserts and Acetabular Cups made of polyethylene (UHMWPE) are compatible (except specific mention) with all HOWMEDICA OSTEONICS Heads of the same diameter.

Coatings
The coatings incorporated on the Restoration ADM HA metal shells consist of titanium plasma spray, and the titanium bond layer overlaid with a layer of hydroxylapatite. These materials are certified to ASTM and/or ISO Standards:

Material:	ASTM Standard / ISO Standard
Titanium Commercially Pure (CP)	F1580 / 5832-2
Hydroxylapatite (powder)	F1185

Label Information
The product label provides information regarding specific material(s) from which the product is manufactured.

INDICATIONS
The indications for use for total hip arthroplasty include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and,
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6. Dislocation risks

RESTORATION ADM HA Cups and MDM Liners are intended for cementless use only.

CONTRAINDICATIONS
1) Overt infection;
2) Distant foci of infections (which may cause hematogenous spread to the implant site);
3) Rapid disease progression as manifested by joint destruction or bone resorption apparent on roentgenogram;
4) Skeletally immature patients; and
5) Cases where there is a loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1) Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2) Osteoporosis;
3) Metabolic disorders which may impair bone formation; and
4) Osteomalacia.

WARNINGS

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in service life of the prosthetic implant. The surgeon must be thoroughly familiar with the surgical procedure, instruments, and implant characteristics, prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and condition of the prosthetic components, as well as the condition of the adjoining bone.

Restoration ADM HA Cup is intended for Press-Fit Application only. Secure fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device. Press-fit acetabular components require a precise operative technique and use of specified instruments. Adequate acetabular preparation is important for the success of the procedure.

Hydroxylapatite coated implants are not intended for use with bone cement.

Modular Acetabular Shell/Liner. Fixation devices, when used, should be fully seated to help assure stable fixation of the shell, and to help avoid interference with the liner component. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell. Debris may inhibit the liner from functioning correctly and may increase polyethylene wear.

Metal Components

Questions have been raised regarding some of the alloys utilized to produce orthopedic implants. The alloys contain some metallic components that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Some hypotheses have been stated in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon.

Ultra-High-Molecular-Weight Polyethylene (UHMWPE)

Polyethylene Wear. As would be expected, wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to relatively early revision surgery to replace the worn prosthetic components.

PRECAUTIONS

Information for patients. The surgeon 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.

The surgeon must 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.

The surgeon must warn patients of surgical risks, and inform them of possible adverse effects. The surgeon must warn patients that the device does not replicate the flexibility, strength, reliability, or durability of 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 help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Interaction with Magnetic Resonance Imaging
Restoration ADM & MDM Liner have not been evaluated for safety and compatibility in the MR environment. Restoration ADM & MDM Liner have also not been tested for heating or migration in the MR environment.

Instruments. Specialized instruments are available and must be used to help assure the accurate implantation of prosthetic components.

While rare, intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are more susceptible to fracture. Instruments must be examined for wear, or damage, prior to surgery.

Re-use. An implant must never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Handling. Proper handling of implants is important. The highly polished portion of the implant should not come in contact with hard surfaces.

(See OTHER IMPORTANT INFORMATION section for more information).

ADVERSE EFFECTS

1) With all joint replacements, asymptomatic, localized progressive bone resorption (osteolysis) may occur around, or remote from, the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See IMPORTANT PHYSICIAN INFORMATION section for more information).
2) Although rare, sensitivity/allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.
4) Dislocation and subluxation of implant components can result from improper positioning or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5) Implants can loosen or migrate due to trauma or loss of fixation.
6) Infection can lead to failure of the joint replacement.
7) Fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, and/or duration of service, singularly or in combination.

Intraoperative and early postoperative complications can include:

1) Femoral or acetabular perforation, or fracture;
2) Femoral fracture while seating the device;
3) Damage to blood vessels;
4) Temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
5) Undesirable shortening or lengthening of the limb;
6) Traumatic arthrosis (joint disease caused by trauma) of the knee from intraoperative positioning of the extremity;
7) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction, or death;

8) Hematoma;
9) Delayed wound healing; and
10) Infection.

Late postoperative complications can include:
1) Trochanteric avulsion (tearing away of soft tissue from the bone) as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
2) Trochanteric nonunion due to inadequate reattachment and/or early weight bearing;
3) Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency;
4) Femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
5) Periarticular calcification or ossification, with or without impediment to joint mobility;
6) The following, singularly or in combination can lead to and/or cause decreased range of motion: improper selection or positioning of components, femoral impingement, and/or periarticular calcification; and
7) Progressive bone resorption and osteolysis.

IMPORTANT PHYSICIAN INFORMATION

Bone Resorption and Osteolysis. Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. It has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate from the synovial cavity and into the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

Since osteolysis is frequently asymptomatic, the patient's normal periodic radiographic examination is a good way to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of local lesions which are progressive may necessitate replacement of the prosthetic component(s).

OTHER IMPORTANT INFORMATION

A. Particular attention should be paid when handling those prostheses that have some type of coating, e.g., hydroxylapatite. Contact between the coated surface and cloth or other fibre releasing materials should be avoided in order to minimize contamination of the coated surface with adherent materials. All implants where the coating has been damaged or contaminated should be discarded.

B. **Titanium Plasma Sprayed Devices**

The United States Food and Drug Administration (FDA) believes that reasonable assurance of the safety and effectiveness of components with Titanium Plasma Sprayed surfaces has not yet been established by long term (i.e., nine years and greater) studies. In bench testing, plasma sprayed porous coatings have shown lower mechanical strength and lower resistance to abrasion than sintered cobalt chromium alloy bead coatings or sintered titanium fibre mesh coatings. Clinically, loss

of the titanium plasma sprayed coating could lead to compromise of function or failure of the device, necessitating revision. The FDA has mandated post market surveillance of these devices until such time as a nine year follow up is achieved. Patients receiving these devices should be monitored to ensure that the plasma sprayed device is not failing earlier than reasonably expected due to metal debris, coating spalling or coating delamination. These conditions could result in significant incapacitation and require revision surgery. Short term (i.e., less than four years) clinical data have not identified any significant differences in the clinical failure rate between titanium plasma sprayed porous coated hip systems and hip systems with sintered porous coatings.

C. **Product Label.** See product label for information regarding the specific product referenced in this package insert.

How Supplied

- These products have been sterilized by either gamma radiation or hydrogen peroxide. Refer to the package label for the sterilization method.
- Do NOT resterilize.
- Take care to prevent contamination of any components.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is nonsterile.
- Discard ALL nonsterile or contaminated products per applicable local regulations and hospital protocol.
- 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.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Caution: Federal Law in the USA restricts this device to sale by or on the order of a physician.

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		

ACCOLADE® II FEMORAL STEM

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
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Telephone #: +1 201-831-5000

CE 0086

QIN 4414 Rev. C

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

Sterilized using Irradiation

Sterilized using Hydrogen Peroxide

Sterilized using Ethylene Oxide

Use by Date

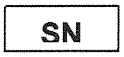
Date of Manufacture

Legal Manufacturer

Authorized Representative in the European Community

Catalog Number

Batch Code



Serial Number

English

ACCOLADE II FEMORAL STEM

DESCRIPTION

Howmedica Osteonics Corp. Accolade II Femoral Hip System is a collarless, tapered wedge stem that is intended for cementless use in primary applications where there is adequate bone stock. It features a plasma-sprayed Hydroxyapatite coating over plasma-sprayed Titanium. See package label for specific product features and the surgical protocol for additional procedural information and product information.

MATERIALS

The device is manufactured from materials that meet the following standards:

Ti6Al4V ELI Alloy	Wrought: ASTM F136 Forged: ASTM F620	Stem
Commercially Pure Titanium	ASTM F1580, ASTM F67	Titanium plasma-sprayed coating
Hydroxyapatite powder	ASTM F1185	HA coating

COMPATIBILITY

- Howmedica Osteonics ACCOLADE II Femoral Stems are compatible with Howmedica Osteonics V40 Taper Femoral Heads made from the following material: CoCr, LFIT CoCr, Alumina, and BIOLOX *delta*.
- Howmedica Osteonics ACCOLADE II Femoral Stems are compatible with Howmedica Osteonics C-Taper Femoral Heads made from the following material when used with the Howmedica Osteonics V40 Taper Adapter Sleeve: Alumina, BIOLOX *delta*.
- Howmedica Osteonics ACCOLADE II Femoral Stems are compatible with Howmedica Osteonics Universal Taper BIOLOX *delta* Femoral Heads when used with a Howmedica Osteonics V40 Taper Universal Adapter Sleeve.
- Howmedica Osteonics ACCOLADE II Femoral Stems are compatible with Howmedica Osteonics Unitrax Unipolar Heads when used with the Unitrax V40 monolithic adapter.
- Howmedica Osteonics ACCOLADE II Femoral Stems cannot be used with femoral heads with an offset greater than +12mm. This is indicated with a visual check (√) on the trunnion of the stem.

INDICATIONS

The indications for use of the total hip replacement prostheses include:

1. noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. nonunions, femoral neck fractures, and trochanteric fractures of the proximal

femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of ACCOLADE II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:

1. When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

ACCOLADE II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

CONTRAINDICATIONS

1. active infection or suspected latent infection in or about the hip joint;
2. bone stock that is inadequate for support or fixation of the prosthesis;
3. skeletal immaturity;
4. any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care; and
5. Obesity. An overweight or obese patient can produce loads on the device that can lead to failure of the fixation of the device or to failure of the device itself.

WARNINGS

- Seat modular femoral head components firmly on the femoral component to prevent dissociation. Machined taper surfaces must be clean and dry to ensure proper seating and assembly. Repeated assembly/disassembly of the head and stem taper could compromise the taper lock.
- Do not substitute another manufacturer's device for any component of the Howmedica Osteonics Total Hip System. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Never reuse an implant, even though it may appear undamaged.
- Discard damaged, mishandled, or contaminated implants.

PRECAUTIONS

- Protect all components from contamination.
- Avoid handling hydroxyapatite coated regions, as it may compromise the effectiveness of the device.
- Do not allow coated surfaces to contact cloth or other fiber-releasing materials.
- Protect polished bearing areas and machined taper surfaces from contact with hard or abrasive surfaces.
- Take care not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Interaction with Magnetic Resonance Imaging

The ACCOLADE II Hip System has not been evaluated for safety and compatibility in the MR environment. The ACCOLADE II Hip System has not been tested for heating or migration in the MR environment.

PATIENT SELECTION

- Proper implant selection is critical to the stability and longevity of the femoral stem implant in hip arthroplasty. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and pre-operative level of health, as well as the surgeon's experience and familiarity with the device. Longevity and stability of the implant may be affected by these factors.
- The smaller sized femoral stem implants are intended for use in patients with smaller intramedullary femoral canals. Their geometry has been reduced to accommodate the anatomy of the smaller intramedullary femoral canal, which thereby decreases their fatigue-strength and load-bearing characteristics. Therefore, patients with high physical activity levels, poor bone quality, or who are overweight are not candidates for the smaller femoral implant stem.
- Patients with high-activity level and/or higher weight patients are at greater risk for implant complications or failures. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.
- The surgeon must evaluate each situation carefully based upon the patient's clinical presentation before making any decisions regarding the selection of the implant.

ADVERSE EFFECTS

- Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total hip components can occur. Early mechanical 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.
- Fatigue fracture of femoral stems has occurred in a small percentage of cases. Stem fracture is more likely to occur in heavy, physically active patients, or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
- Intraoperative fissure, fracture, or perforation of the femur or trochanter can occur due to impaction of the component into the prepared femoral canal. Postoperative femoral fracture can occur due to trauma, the presence of defects, or poor bone stock.
- 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.
- Very small particles from metal and polyethylene components can be shed from the components during normal use and over time. Although most of this debris stays in

the relevant joint (i.e. contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can migrate throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. 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, are unknown. The long-term effects have been theorized to 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 process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
- Systemic Disease: There has been some speculation that there could be an association between migration of debris and as yet unidentified systemic effects. Long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of 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.

- Metal sensitivity reactions have been reported following joint replacement.
- Undesirable shortening or lengthening of the limb.
- 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.
- Peripheral neuropathies, nerve damage, circulatory compromise, and heterotopic bone formation may occur.
- Infection can occur.

Adverse effects may require medical intervention including reoperation, revision, arthrodesis of the involved joint, Girdlestone, or amputation of the limb.

USE AND IMPLANTATION

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
- The Surgical Protocol provides additional procedural information.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Specialized instruments are available and should be used to ensure accurate implantation of prosthetic components.
- To preserve the integrity of the actual implants and their sterile packaging, use the

recommended trial components for size determination, trial reduction and range-of-motion evaluation.

- Proper selection, placement, and fixation of the implant components are critical factors affecting implant service life. The durability of prosthetic implants is affected by many biologic, biomechanic and other extrinsic factors that limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

INFORMATION FOR THE PATIENT

- Surgeons must advise patients of the limitations of the reconstruction and the need to protect the implant from full weight bearing until adequate healing has occurred.
- Surgeons must caution patients to protect the replaced joint from excessive loading, and to follow the physician's instructions regarding activity level, follow-up care, and treatment. Advise patients that the device cannot be expected to withstand the same activity levels and loads as a normal healthy joint, that the implant can break or become damaged as a result of excessive loading, and that the device has a finite service life and may need to be replaced in the future.
- Surgeons must warn the patient of surgical risks and possible adverse effects.
- Dental procedures, endoscopic examinations and other minor surgical procedures have been associated with transient bacteremia. Instruct the patient to inform their doctors that they have an artificial hip replacement, so that their doctors can decide whether to use antibiotic prophylaxis for such procedures.

HOW SUPPLIED

- These products have been sterilized by gamma radiation.
- Do **NOT** resterilize.
- Take care to prevent contamination of any components.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is nonsterile.
- Discard ALL nonsterile or contaminated product.
- Device should not be used after the expiry date displayed on the label as packaging had 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.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Caution: Federal Law in the USA restricts this device to sale by or on the order of a physician.

owners or holders.
BIOLOX® delta is a registered trademark of CeramTec AG.
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:

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

Appendix D

FDA 510(k) Clearance Letters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

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

OCT 2 3 2007

Re: K072020
Trade/Device Name: Restoration Anatomic™ Dual Mobility (ADM) System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code(s): MEH, LZO
Dated: July 20, 2007
Received: July 23, 2007

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 forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

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

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K072020

Device Name: Restoration™ ADM System

Indications for Use:

The indications for use of the total hip replacement prostheses include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed;
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6) Dislocation risks

This acetabular cup is intended for cementless use only.

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)

Barbara Quelly

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072020

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Avital Merl-Margulies
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

DEC 1 8 2009

Re: K093644
Trade/Device Name: Restoration® ADM System X3® Acetabular Insert
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: MEH, LZO
Dated: November 24, 2009
Received: November 25, 2009

Dear Ms. Merl-Margulies:

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.

.3353

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K093644

Device Name: Restoration® ADM System X3® Acetabular Insert

Indications for Use:

The indications for use of the total hip arthroplasty include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed;
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6) Dislocation risks

This acetabular cup is intended for cementless use only.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093644

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 2 1 2011

Howmedica Osteonics Corp.
% Ms. Estela Celi
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K103479
Trade/Device Name: Novel Tapered Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO, LWJ, KWZ, KWY, KWL, JDI, LPH
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. Celi:

This letter corrects our substantially equivalent letter of March 10, 2011.
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 (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 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2010

STRYKER CORP
HOWMEDICA OSTEONICS CORP
325 CORPORATE DRIVE
MAHWAH, NEW JERSEY 07430
UNITED STATES
ATTN: ESTELA CELI

510k Number: K103479
Received: 11/26/2010
Product: NOVEL TAPERED HIP STEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

stryker
Howmedica
OSTEONICS

February 10, 2011

Via Federal Express

Office of Device Evaluation (510(k))
Document Mail Center (WO66-G609)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Traditional Premarket Notification K103479: Novel Tapered Hip Stem

Ladies and Gentleman:

Howmedica Osteonics is requesting a one hundred and eighty (180) day extension to respond to the deficiency email dated 2/1/11. We anticipate submission of a response to the deficiency letter on or before August 9, 2011. Thank you for your prompt attention to this request.

Sincerely,
Howmedica Osteonics Corp.

Estela Celi

Estela Celi
Regulatory Affairs Associate

Indications for Use

510(k) Number (if known): K103479

Device Name: Novel Tapered Hip Stem (aka Accolade II Femoral Hip Stem)

Indications for Use:

The indications for use of the total hip replacement prostheses include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Nonunions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Accolade II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:

1. When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103479

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Appendix E

Model Informed Patient Consent

Model Informed Patient Consent

I. Study Title: Post-market Study of the Stryker Orthopaedics Restoration® Anatomic Dual Mobility (ADM) X3® Acetabular System with Long Term Data Collection for the Accolade® II Hip Stem.

II. Description of the Study

You have been asked to take part in this research study because your physician has determined that you need surgery to replace your hip joint. A total of approximately 350 subjects from up to 12 different clinics will be participating in this study.

The purpose of this study is to evaluate the success rate of cementless primary hip replacement with the Restoration® ADM X3® Acetabular System as compared to other primary hip systems in the literature, through absence of femoral head dislocation at 10 years postoperative. We (Stryker Orthopaedics, implant manufacturer and sponsor of the study, and your physician) are doing this study to find out if Stryker Orthopaedics Restoration® ADM X3® Acetabular System is at least as good as other primary hip implants.

You will be asked some questions during this visit and based on study specific criteria, you may or may not be selected to participate in the study.

Meeting all of the above criteria does not guarantee participation in the study. Further consideration 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 you would like to participate.

If selected, your participation in the study will last 10 years. You will be evaluated for this study during a preoperative visit, during surgery, as well as 6 weeks, 1 year, 2 years, 3 years, 4 years, 5 years, 7 years and 10 years after surgery.

During the preoperative visit you will be asked to complete three general health assessment questionnaires in addition to the standard information and x-rays that your doctor will collect during your office visit.

You will undergo surgery and your doctor will also provide us with the details of your surgery.

During your 6-week, 1, 2, 3, 4 and 5-year follow-up visits, and optionally at your 7 and 10-year follow-up visits, your doctor will assess the function of your hip and take three x-rays. This set of x-rays is part of the standard care following hip surgery, and would be performed in the same manner if you were not involved in the study. Your doctor will inform you where the x-rays will be done. In addition, your doctor will ask you to fill out the two general health assessment questionnaires at your 6 week, 1, 2, 3, 4 and 5-year follow-up visits, and optionally at your 7 and 10-year visits.

Finally, you will be asked to complete a short questionnaire regarding your satisfaction with the results of your hip replacement at 6, 7, 8, 9, and 10 years after surgery.

III. Postoperative Condition and Care

Your doctor will give you specific instructions regarding your care and rehabilitation after your surgery. As with any surgery, your body takes time to heal. That amount of time will be related to the extent of the surgical procedure and your general physical condition. During this period of healing, you may experience postoperative pain, perhaps lasting several months after the operation.

You will be told to use walking aids (crutches, walker or cane) for a period of time after your surgery. The use of these walking aids will lessen pressure and weight loads on your hip, which is thought to increase the chances for a stable implant. You have been informed that you must follow your physician's orders, including those regarding the use of walking aids.

The goal of this surgery is to lessen pain and increase your hip function. You will need to see your physician at 6 weeks, 1, 2, 3, 4 and 5 years after your surgery, and optionally at 7 and 10 years after your surgery, for evaluation of your artificial hip joint.

IV. Foreseeable Risks and Discomforts

This study involves the routine assessment of a primary hip replacement procedure. The Food and Drug Administration (FDA) has cleared the device used in this study for sale in the United States. There are no additional risks associated with participating in this study over and above that of the primary hip surgery. You may need to spend a little more time in the doctor's office to fill out paperwork. If at any time new information is developed during this research study which may affect your willingness to participate, the information will be provided to you.

There are, however, standard risks associated with hip surgery. These include but are not limited to: moderate to severe pain; crack/fracture (breakage) of femoral (thigh) or acetabular (pelvic) bones or components; migration (movement) of components; subsidence (sinking) of components; dislocation (to move out of normal position) of components; sensitivity to metal components (femoral [thigh] and acetabular [pelvic]); revision (removal) of one or more of the components; loosening and infection; wear (rubbing) of the components which could lead to bone loss; peripheral neuropathies (any disorder of the nerves involving your legs); nerve damage; abnormal bone formation; circulatory compromise (changes in circulation related to your heart, blood and lymph vessels, to varying degrees); genitourinary disorders (related to urination); gastrointestinal disorders (related to the stomach and intestines); vascular disorders (related to blood vessels: including thrombus [blood clot]); bronchopulmonary disorders (related to the bronchi tubes and lungs, such as pneumonia); emboli (plugged vessel); myocardial infarction (heart attack) or death.

V. Potential Benefits

While there is no guarantee that you will personally benefit from inclusion in this study, information gathered in this study may benefit others undergoing primary hip surgery in the future.

VI. Alternate Treatment

You have discussed alternative treatments with your surgeon which include but are not limited to: conservative non-surgical treatment, cemented total hip replacement utilizing commercially available components, hip fusion or no treatment at all.

You may decline to participate in this study. This will not change any procedures associated with your hip surgery. Your physician can provide detailed information about this treatment and the benefits of various treatment options available to you. You should feel free to discuss your alternatives with your physician.

VII. Financial Disclosure

Your doctor and/or the research institution may receive compensation from the manufacturer of your implant device(s) to cover the time and/or expenses associated with this Study or for other services. If you require any further information please consult your doctor or his staff about this issue.

VIII. Confidentiality

If you consent to participate in this study, your medical records and identity will be kept confidential to the extent permitted by law and will not be released without your written permission. By signing this consent form, you agree to allow representatives from the study sponsor to review your medical records. Some of this information will be provided to the study sponsor and its agents and contractors, and as required by law, review boards and other people who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. Your name and identity will not be revealed in those reports.

IX. Cost to Participate in Study

Your procedure is a routine primary hip surgery and should be covered by your insurance carrier. You will not be paid for participating in this study.

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

X. Device Retrieval Analysis Study

I understand that the Stryker Orthopaedics Restoration® ADM X3® Acetabular System Study has a protocol for the analysis of retrieved devices in the event that any study component(s) that I have had implanted by Dr. <Investigator's Name> are removed during the course of the investigation.

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

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

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

I understand that, except for sending my retrieved study component(s) to The Cleveland Clinic Foundation and Stryker Orthopaedics, my retrieved study component(s) will not be released to outside parties.

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

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

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

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

_____ _____

Signature of Subject/Legal Representative Date

XI. Clinical Trial Website Posting

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

XII. Injury Related Compensation and Medical Treatment

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

XIII. Access to Data and Confidentiality

By participating in this study, you are authorizing your physician and his/her staff to provide your health information to the sponsor, its agents and contractors, and as required by law, review boards and other people who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. This health information includes all information collected during the research. It may also include relevant health information in your medical records that may have been collected prior to your involvement in this research study.

The sponsor will only collect that information which is necessary to support the objectives of the research, and will take precautions to ensure that data received has your identifying information (name, address, etc.) removed as much as possible. National privacy laws no longer cover use or re-disclosure of your health information, once received by the sponsor. However, in the case that some identified information is received, the sponsor will ensure that any identifying information will not be reported.

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

This permission does not have an ending date, but you may take back this permission to release your health information at any time by notifying your physician in writing. Understand that doing so will have no effect on actions taken before that time. This consent, authorizing that your health information may be provided to those indicated, must be signed in order for you to participate in this research study. If this consent is revoked you can no longer participate in this research study. In any case, your authorization to release individually identifiable information will expire at the end of this study.

XIIV. Contact People

If you have any questions about this study or about your rights as a research subject, please contact: <names and phone numbers>. If you have a research-related injury, you should immediately contact <names and phone numbers>.

XV. Participation

Your participation in this study is strictly voluntary. Refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled. You may

also withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

By signing and dating this form below, you are indicating that you have read and reviewed all sections of this Informed Consent Form, you have had all your questions answered, and you voluntarily consent to participate in this research study. If you do not sign this form, you will not be allowed to participate in the research study.

_____
Printed name of Subject/Legal Representative

_____ _____
Signature of Subject/Legal Representative Date Signed

(additional signatures that may be required):

_____ _____
Signature of Person conducting the consent process Date Signed

_____ _____
Signature of Investigator Date Signed

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

Appendix F

Specifications for Electronic Case Report Forms

Restoration®ADM X3®Acetabular System

INCLUSION / EXCLUSION

GENERAL INFORMATION

SUBJECT INITIALS:	OPERATIVE SIDE:	DATE INFORMED CONSENT SIGNED:	SUBJECT IDENTIFIER:
	◯ Right ◯ Left	(DD-MMM-YYYY)	

I. INCLUSION CRITERIA

	Yes	No	
A.	◯	◯	Patient has signed an IRB/EC approved study specific Informed Patient Consent Form.
B.	◯	◯	Patient is a male or non-pregnant female, skeletally mature and age 18 - 75 years at time of study device implantation.
C.	◯	◯	Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
D.	◯	◯	Patient is a candidate for a primary cementless acetabular replacement.
E.	◯	◯	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.**

II. EXCLUSION CRITERIA

	Yes	No	
F.	◯	◯	Patient has a Body Mass Index (BMI) ≥ 40.
G.	◯	◯	Patient has an active or suspected latent infection in or about the affected hip joint at time of study device implantation.
H.	◯	◯	Patient has a neuromuscular or neurosensory deficiency, which limits ability to evaluate the safety and efficacy of the device.
I.	◯	◯	Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's disease) leading to progressive bone deterioration.
J.	◯	◯	Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days).
K.	◯	◯	Patient requires revision surgery of a previously implanted total hip replacement or hip fusion to the affected joint.
L.	◯	◯	Patient has a known sensitivity to device materials.
M.	◯	◯	Patient is a prisoner.

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

III. COMMENTS

Restoration®ADM X3®Acetabular System

DEMOGRAPHICS

GENERAL INFORMATION

SUBJECT INITIALS: _____

VISIT DATE: _____ (DD-MMM-YYYY)

SUBJECT ID: _____

I. DEMOGRAPHICS

A. DATE OF BIRTH: _____ (DD-MMM-YYYY)

Select appropriate Unit of Measure for Height and Weight.

◯ US / English ◯ Metric

B. HEIGHT: _____ inches

C. WEIGHT: _____ kgs

BMI _____ Auto Calculate Read Only

D. EDUCATION LEVEL:

◯ Less Than High School
◯ High School Diploma
◯ Greater Than High School

E. EMPLOYMENT STATUS:

◯ Working
◯ Not Working

F. GENDER:

◯ Male
◯ Female

G. ETHNICITY:

◯ Hispanic or Latino origin
◯ Not Hispanic or Latino origin

H. RACE:

☐ American Indian or Alaskan native
☐ Asian
☐ Black or African
☐ Native Hawaiian or other Pacific Islander
☐ White

II. CIGARETTE AND ALCOHOL USE

I. CIGARETTE USE: If the subject is a current or past cigar and/or pipe smoker, please select "Non-smoker" and enter a comment on Page 2 of this CRF.

◯ Non-smoker

◯ Current cigarette smoker
(Specify # Packs/Day and # Years below)

◯ Ex-cigarette smoker
(Specify # Packs/Day, # Years, and Date Stopped)

PACKS/DAY: _____ # YEARS: _____

Date Stopped _____ (DD-MMM-YYYY)

J. ALCOHOL USE:

◯ Have never had alcohol
◯ Have not had alcohol in the last year
◯ Less than 3 drinks a week
◯ 3 -7 drinks a week
◯ 8 - 14 drinks a week
◯ 15+ drinks a week

III. DIAGNOSIS

K. INITIAL DIAGNOSIS:

◯ Osteoarthritis ◯ Traumatic Arthritis ◯ Avascular Necrosis

◯ Other (Specify) _____

IV. PRESENT MEDICAL STATUS

L. CONCURRENT MEDICAL CONDITION:

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

V. COMMENTS

Reason for Save

Verification / Confirmation Method

Restoration®ADM X3®Acetabular System

LOWER EXTREMITY ACTIVITY SCALE (LEAS)

GENERAL INFORMATION

SUBJECT INITIALS: **VISIT:** **SUBJECT ID:**

I. LOWER EXTREMITY ACTIVITY SCALE

Enter data as completed by the subject per paper questionnaire.

1. ◯ I am confined to bed all day.
2. ◯ I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc.).
3. ◯ I am either in bed or sitting in a chair most of the day.
4. ◯ I sit most of the day, except for minimal transfer activities, no walking or standing.
5. ◯ I sit most of the day, but I stand occasionally and walk a minimal amount in my house. (I may rarely leave the house for an appointment and may require the use of a wheelchair or scooter for transportation.)
6. ◯ I walk around my house to a moderate degree but I don't leave the house on a regular basis. I may leave the house occasionally for an appointment.
7. ◯ I walk around my house and go outside at will, walking one or two blocks at a time.
8. ◯ I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting).
9. ◯ I am up and about at will in my house and can go out and walk as much as I would like with no restrictions (weather permitting).
10. I am up and about at will in my house and outside. I also work outside the house in a:
    (Please check the best description of your work level.)
    - ◯ minimally active job
    - ◯ moderately active job
    - ◯ extremely active job
11. I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming:
    (Please check the best description of how often you participate in this activity.)
    - ◯ occasionally (2-3 times per month)
    - ◯ 2-3 times per week
    - ◯ daily
12. I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports:
    (Please check the best description of how often you participate in this activity.)
    - ◯ occasionally (2-3 times per month)
    - ◯ 2-3 times per week
    - ◯ daily

II. COMMENTS

Subject Initials are present on paper CRF?

◯ Yes ◯ No

SUBJECT INITIALS DATE:
Record the date the subject completed the questionnaire.
(DD-MMM-YYYY)

Reason for Save

Verification / Confirmation Method

Restoration®ADM X3®Acetabular System

SF - 12 v2

GENERAL INFORMATION

SUBJECT INITIALS: _____ **VISIT:** _____ **SUBJECT ID:** _____

I. SF-12™ HEALTH SURVEY STANDARD VERSION

Enter data as completed by the subject per paper questionnaire.

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

Excellent	Very Good	Good	Fair	Poor
○	○	○	○	○

---

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

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

---

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

a. **Accomplished less than you would like**

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

b. **Were limited in the kind of work or other activities**

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

---

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

a. **Accomplished less than you would like**

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

b. **Did work or other activities less carefully than usual**

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

II. SF-12 (CONTINUED)

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

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

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

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

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

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

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

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

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

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

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

COMMENTS

Subject Initials are present on paper CRF?

○ Yes ○ No

SUBJECT INITIALS DATE:
Record the date the subject completed the questionnaire.
(DD-MMM-YYYY)

Reason for Save

Verification / Confirmation Method

Restoration® ADM X3® Acetabular System

PRE-OP FUNCTIONAL EVALUATION

GENERAL INFORMATION

SUBJECT INITIALS:

VISIT DATE:
(DD-MMM-YYYY)

SUBJECT ID:

I. PAIN

A. PAIN

- ◯ None, or ignores it
- ◯ Slight, occasional, no compromise in activities
- ◯ Mild, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin
- ◯ Moderate pain, tolerable but makes concessions to pain. Some limitations of ordinary activity or work. May require occasional pain medication stronger than aspirin
- ◯ Marked pain, serious limitation of activities
- ◯ Totally disabled, crippled, pain in bed, bedridden

II. FUNCTION / GAIT

B. LIMP

- ◯ None
- ◯ Slight
- ◯ Moderate
- ◯ Severe or unable to walk

C. SUPPORT

- ◯ None
- ◯ Cane, long walks
- ◯ Cane, most of the time
- ◯ One crutch
- ◯ Two canes
- ◯ Two crutches, walker or unable to walk

D. DISTANCE WALKED

- ◯ Unlimited
- ◯ Six blocks
- ◯ Two or three blocks
- ◯ Indoors only
- ◯ Bed and chair only

III. FUNCTIONAL ACTIVITIES

E. STAIRS

- ◯ Normally without using a rail
- ◯ Normally using a railing
- ◯ In any manner
- ◯ Unable to use stairs

F. SOCKS / SHOES

- ◯ With ease
- ◯ With difficulty
- ◯ Unable

G. SITTING

- ◯ Any chair, 1 hour
- ◯ High chair, 1/2 hour
- ◯ Unable to sit comfortably in any chair

H. PUBLIC TRANSPORTATION

- ◯ Able to use
- ◯ Not able to use

I. ABSENCE OF DEFORMITY (Operative side only)

Select "Yes" to indicate there is no deformity. Select "No" to indicate there **is** a deformity.

	Yes	No
Fixed flexion contracture < 30°	◯	◯
Fixed adduction < 10°	◯	◯
Fixed internal rotation in extension < 10°	◯	◯
Leg length discrepancy < 3.2 cm	◯	◯

If no leg length discrepancy exists record 0 cm and check Yes. _____ cm

HHS

Auto Calculate Read Only

J. RANGE OF MOTION (Operative side only)

Permanent (Fixed) Flexion	°
Flexion to	°
Abduction to	°
Adduction to	°
External Rotation in Extension to	°
Internal Rotation in Extension to	°

IV. COMMENTS

Reason for Save

Verification / Confirmation Method

Restoration®ADM X3®Acetabular System

SURGICAL DETAILS

GENERAL INFORMATION

SUBJECT INITIALS: _____ **SURGERY DATE:** _____ (DD-MMM-YYYY) **SUBJECT ID:** _____

Submit Surgical Details CRF only if surgery is performed and subject receives study device.

I. SURGICAL DETAILS

A. APPROACH

- ◯ Anterior/ Anterolateral
- ◯ Posterior/ Posterolateral
- ◯ Dual Incision
- ◯ Lateral

B. MUSCLE REPAIR OR REATTACHMENT REQUIRED?

- ◯ Yes* *If Yes, which muscle group?
- ◯ No
  - ☐ External Rotators
  - ☐ Gluteus Medius
  - ☐ Other _____

C. NAVIGATION USED?

- ◯ Yes
- ◯ No

D. INCISION LENGTH

_____ cm

E. DURATION OF SURGERY

Skin to Skin _____ minutes

F. ESTIMATED BLOOD LOSS

_____ cc

II. PROSTHESIS

G. PROSTHESES -

Upload a PDF copy of the component label(s) implanted.

Please go to Subject Information screen and enter data in Products tab.

Acetabular Shell

Acetabular Insert

Femoral Bearing Head

Modular Neck

Modular / Femoral Stem

H. OTHER? ◯ Yes* ◯ No

*If Yes, specify and attach a copy of the label(s):

Add Row / Reset	Other (Specify)	Reference #	Lot #
x			

I. INTRAOPERATIVE COMPLICATION?

If Yes, complete AE form. ◯ Yes ◯ No

J. DISCHARGED TO: (Check One)

- ◯ Skilled Nursing Facility
- ◯ Chronic Care Center
- ◯ Rehabilitation Unit
- ◯ Home
- ◯ Other: (Specify) _____

Discharge Date: _____ DD-MMM-YYYY

III. COMMENTS

Reason for Save _____

Verification / Confirmation Method _____

Submit

Restoration® ADM X3® Acetabular System
POST-OP FUNCTIONAL EVALUATION

GENERAL INFORMATION

SUBJECT INITIALS:	VISIT DATE:	VISIT:	SUBJECT IDENTIFIER:
	(DD-MMM-YYYY)		

I. PAIN

A. PAIN

- ◯ None, or ignores it
- ◯ Slight, occasional, no compromise in activities
- ◯ Mild, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin
- ◯ Moderate pain, tolerable but makes concessions to pain. Some limitations of ordinary activity or work. May require occasional pain medication stronger than aspirin
- ◯ Marked pain, serious limitation of activities
- ◯ Totally disabled, crippled, pain in bed, bedridden

II. FUNCTION / GAIT

B. LIMP

- ◯ None
- ◯ Slight
- ◯ Moderate
- ◯ Severe or unable to walk

C. SUPPORT

- ◯ None
- ◯ Cane, long walks
- ◯ Cane, most of the time
- ◯ One crutch
- ◯ Two canes
- ◯ Two crutches, walker or unable to walk

D. DISTANCE WALKED

- ◯ Unlimited
- ◯ Six blocks
- ◯ Two or three blocks
- ◯ Indoors only
- ◯ Bed and chair only

III. FUNCTIONAL ACTIVITIES

E. STAIRS

- ◯ Normally without using a rail
- ◯ Normally using a railing
- ◯ In any manner
- ◯ Unable to use stairs

F. SOCKS / SHOES

- ◯ With ease
- ◯ With difficulty
- ◯ Unable

G. SITTING

- ◯ Any chair, 1 hour
- ◯ High chair, 1/2 hour
- ◯ Unable to sit comfortably in any chair

H. PUBLIC TRANSPORTATION

- ◯ Able to use
- ◯ Not able to use

I. ABSENCE OF DEFORMITY (Operative side only)

Select "Yes" to indicate there is no deformity. Select "No" to indicate there **is** a deformity.

	Yes	No
Fixed flexion contracture < 30°	◯	◯
Fixed adduction < 10°	◯	◯
Fixed internal rotation in extension < 10°	◯	◯
Leg length discrepancy < 3.2 cm	◯	◯

If no leg length discrepancy exists record 0 cm and check Yes. _____ cm

J. RANGE OF MOTION (Operative side only)

Permanent (Fixed) Flexion	°
Flexion to	°
Abduction to	°
Adduction to	°
External Rotation in Extension to	°
Internal Rotation in Extension to	°

HHS

Auto Calculate Read Only

IV. EVENTS

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

*If Yes, complete an AE form for each.

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

L. Has the subject seen a doctor for any medical event since the last visit? ◯ Yes* ◯ No

*If Yes, specify:

M. Has the subject been hospitalized for any elective surgery since the last visit? ◯ Yes* ◯ No

*If Yes, specify (check all that apply)

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

☐ Ipsilateral Shoulder ☐ Cataract ☐ Other (Specify)

*Provide Details

N. Is anything currently affecting the subject's function? ◯ Yes* ◯ No

*If Yes, specify:

V. COMMENTS

Reason for Save

Verification / Confirmation Method

Restoration® ADM X3® Acetabular System

FOLLOW-UP QUESTIONNAIRE

GENERAL INFORMATION

SUBJECT INITIALS: **VISIT:** **SUBJECT ID:**

QUESTIONNAIRE COMPLETED BY: ◯ Visit ◯ Mail ◯ Phone

I. HIP QUESTIONS

1. Do you have any pain in your hip that has the study hip replacement? ◯ YES ◯ NO

Subject comment:

Coordinator comment:

2. Are you satisfied with the results of your study hip replacement? ◯ YES ◯ NO

Subject comment:

Coordinator comment:

3. Have you had any surgery on your study hip since your last study required visit/contact? ◯ YES ◯ NO

Subject comment:

Coordinator comment:

4. Has your study hip dislocated since your last study required visit/contact? ◯ YES ◯ NO

Subject comment:

Coordinator comment:

Coordinator: Review all responses to determine if an AE has occurred and complete an AE f

COMMENTS

Subject initials are present on paper CRF?

If the subject completed this questionnaire over the phone please check Yes.

◯ YES ◯ NO

DATE: (DD-MMM-YYYY)

Reason for Save

Verification / Confirmation Method

Submit

Restoration® ADM X3® Acetabular System

EQ-5D

GENERAL INFORMATION

SUBJECT INITIALS: **VISIT:** **SUBJECT ID:**

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

Mobility

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

Self-Care

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

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

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

Pain / Discomfort

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

Anxiety / Depression

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

EQ VAS SCORE

Enter value marked by subject from paper CRF (0-100).

COMMENTS

Reason for Save

Verification / Confirmation Method

Subject Initials are present on paper CRF?

◯ Yes ◯ No

DATE OF ASSESSMENT:

(DD-MMM-YYYY)

Restoration®ADM X3®Acetabular System

NOTICE OF PROTOCOL DEVIATION

GENERAL INFORMATION

SUBJECT INITIALS:

DATE OF DEVIATION:

(DD-MMM-YYYY)

SUBJECT ID:

I. DEVIATION INFORMATION

A. TYPE OF DEVIATION

- ◯ **Informed Consent:**
  - ◯ Study procedures performed prior to informed consent
  - ◯ Incorrect informed consent version used
  - ◯ Other
- ◯ **Inclusion / Exclusion:** Subject enrolled does not meet the Inclusion / Exclusion criteria
- ◯ **Treatment:** Protocol specified study component(s) not implanted (Check all that apply)
  - ☐ Acetabular Shell*
  - ☐ Acetabular Insert*
  - ☐ Femoral Bearing Head
  - ☐ Modular Neck
  - ☐ Modular / Femoral Stem

  * Complete Study Termination form
- ◯ **Evaluation(s):** (Specify one visit below)

VISIT :

◯ Pre-Op	◯ 6 Week	◯ 1 Year	◯ 2 Year	◯ 3 Year	◯ 4 Year	◯ 5 Year	◯ 6 Year	◯ 7 Year	◯ 8 Year	◯ 9 Year	◯ 10 Year

- ◯ Missed entire visit (Select if entire visit did not occur; no CRF and X-ray completed)
- ◯ Deviation in visit (Check all that apply and specify)
  - ☐ Required form(s)/X-ray(s) not done
  - ☐ Evaluation(s) occurred outside of protocol specified time window
  - ☐ Unevaluable X-ray (i.e. unreadable/poor quality)

(If Deviation in visit, specify each form/X-ray)

- ☐ Follow-up Questionnaire
- ☐ Functional Evaluation
- ☐ LEAS
- ☐ SF-12
- ☐ X-ray - A/P Pelvis
- ☐ X-ray - Lateral

- ◯ **Serious Adverse Event reported to Sponsor after 24 hours of knowledge of event**
- ◯ **Other:**

B. Briefly describe the deviation and why this occurred.

COMMENTS

Reason for Save

Verification / Confirmation Method

Restoration® ADM X3® Acetabular System

ADVERSE EVENT

GENERAL INFORMATION

SUBJECT INITIALS:

ONSET DATE:

(DD-MMM-YYYY)

SUBJECT ID:

I. DESCRIPTION

A. OPERATIVE SITE EVENTS **(Check one event in Section A or Section B)**

- ◯ Acetabular Component Loosening
- ◯ Acetabular Insert Crack / Fracture
- ◯ Acetabular Migration (If > 3mm)
- ◯ Acetabular Shell Crack / Fracture
- ◯ Deep Joint Infection
- ◯ Device Allergic Reaction
- ◯ Femoral Bearing Head Crack / Fracture
- ◯ Femoral Component Loosening
- ◯ Femoral Component Subsidence
- ◯ Femoral Head Dislocation
- ◯ Femoral Neck Crack / Fracture
- ◯ Femoral Stem Crack / Fracture
- ◯ Heterotopic Bone Formation (Type III / IV)
- ◯ Hip Pain
- ◯ Iliopsoas Tendon Impingement
- ◯ Intra-Prosthetic Dislocation
- ◯ Nerve Palsy
- ◯ Osteolysis
- ◯ Reflex Sympathetic Dystrophy (RSD)
- ◯ Soft Tissue Trauma
- ◯ Superficial Wound Infection
- ◯ Tendonitis
- ◯ Thigh Pain
- ◯ Trochanteric Bursitis
- ◯ Trochanteric Crack / Fracture
- ◯ Trochanteric Non-Union
- ◯ Wound Hematoma
- ◯ Other (Specify)

Adverse Event Code

Adverse Event Description

B. SYSTEMIC EVENTS

- ◯ Cancer (Specify)
- ◯ Cardiovascular (Specify)
- ◯ Dermatologic (Specify)
- ◯ Digestive (Specify)
- ◯ DVT
- ◯ Musculoskeletal (Specify)
- ◯ Neurologic (Specify)
- ◯ Pulmonary Embolism
- ◯ Respiratory (Specify)
- ◯ Thrombophlebitis
- ◯ Trauma (Specify)
- ◯ Urogenital (Specify)
- ◯ Other (Specify)

C. WHEN DID THE EVENT OCCUR? ◯ Pre-Op ◯ Intra-Op ◯ Post-Op

II. COMPLICATION / CONCURRENT MEDICAL EVENT

D. DESCRIBE CIRCUMSTANCES, INCLUDING HISTORY OR CAUSATIVE EVENT. SPECIFY SIGNS, SYMPTOMS AND DISEASES.

E. DEVICE RELATED?

◯ Yes* ◯ No ◯ Uncertain*

*** If Yes or Uncertain, please explain and upload applicable de-identified source documentation to the Subject Binder.**

F. SERIOUSNESS Does this event meet the definition of serious? ◯ Yes* ◯ No *** If Yes, check all that apply.**

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

* Specify when Adverse Event became SERIOUS:

If Serious date is the same as Onset date, enter Onset date.

(DD-MMM-YYYY)

If Serious, please upload applicable de-identified source documentation to the Subject Binder.

III. TREATMENT

◯ Yes* ◯ No * If Yes, specify below

REVISIONS / REMOVALS: (Check all that apply)

For Stryker Implants, submit PER form and implant(s) to Stryker.

Date of Treatment (DD-MMM-YYYY)

- ☐ Acetabular Shell (Complete Study Termination Form)
- ☐ Acetabular Insert (Complete Study Termination Form)
- ☐ Femoral Bearing Head
- ☐ Modular Neck
- ☐ Modular / Femoral Stem
- ☐ Other

RE-OPERATIONS: (Specify)

Re-operations are for study hip only and do not include revisions or removals.

(DD-MMM-YYYY)

- ☐
- ☐

OTHER TREATMENTS: (Specify) **ANESTHESIA USED?** ◯ Yes ◯ No

☐ Add Row Reset

Diagnostic tests are not considered Treatments. Do not include X-rays and MRIs.

(DD-MMM-YYYY)

x

RESOLUTION OF EVENT:

- ◯ Unresolved as of
- ◯ Resolved as of

(DD-MMM-YYYY)

* Update this information if the Event has been resolved.

IV. COMMENTS

FOR STRYKER USE ONLY

PER #

Reason for Save

Verification / Confirmation Method

Restoration® ADM X3® Acetabular System

STUDY TERMINATION

GENERAL INFORMATION

SUBJECT INITIALS:	TERMINATION DATE:	SUBJECT ID:
	(DD-MMM-YYYY)	

I. STUDY TERMINATION

A. DID SUBJECT COMPLETE STUDY ACCORDING TO PROTOCOL?

◯ Yes ◯ No* *If No, answer questions B and C.
If Yes, enter Termination Date as the date of the subject's last evaluation.

B. **CHECK ONE PRIMARY REASON BELOW:**

◯ Death (Complete AE form)
Enter date of death as the Termination Date.

◯ Investigative site terminated (Inform the IRB and provide Stryker with a copy of IRB acknowledgement.)
Enter date of study close-out visit as the Termination Date.

◯ Lost to follow-up
Enter date of Stryker termination approval given as the Termination Date.

List efforts to contact subject:

1st phone call:		(DD-MMM-YYYY)
2nd phone call:		(DD-MMM-YYYY)
3rd phone call:		(DD-MMM-YYYY)
Certified letter sent		(DD-MMM-YYYY)

Additional efforts:

◯ Revision/Removal of Study Device (Complete AE and PER forms)
Enter date of revision / removal procedure as the Termination Date.

◯ Study Device Not implanted (Specify below)
Enter date of surgery as the Termination Date.

◯ Subject Withdrawal Select if subject voluntarily withdrew from the study.
Enter date subject notified site of withdrawal as the Termination Date.

◯ Surgery Not Performed (Specify below)
Enter date of surgeon termination or surgery cancellation as the Termination Date.

◯ Other (Specify below)

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

II. COMMENTS

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