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Orthopaedics

Rejuvenate® Modular Hip System Outcomes Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center study of the outcomes of the Rejuvenate® Modular Hip System

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Study Product: *Rejuvenate® Modular Hip System*

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Protocol Change History

Version	Description	Changed By
1.0 10/7/2009	New	Diana F. Doumato

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List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
AP	Anteroposterior
BMI	Body Mass Index
CRF	Case Report Form
CSA	Clinical Study Associate
CSM	Clinical Study Manager
DCF	Data Clarification Form
DCR	Data Clarification Request
EC	Ethics Committee
GCP	Good Clinical Practice
HHS	Harris Hip Score
HIPAA	Health Insurance Portability and Accountability Act
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LEAS	Lower Extremity Activity Scale
NIDJD	Non-Inflammatory Degenerative Joint Disease
PER	Product Experience Report
PI	Primary Investigator
QOL	Quality of Life
ROM	Range of Motion
SAE	Serious Adverse Event
SC	Study Coordinator
SF-12	Short Form-12
THR	Total Hip Replacement
UADE	Unanticipated Adverse Device Effect
UHMWPE	Ultra High Molecular Weight Polyethylene

Study Synopsis

Title	A prospective, post-market, multi-center study of the outcomes of the Rejuvenate® Modular Hip System
Short Title	Rejuvenate® Modular Outcomes Study
Protocol Number	68
Phase	Post-market
Methodology	This study will be a prospective, non-randomized evaluation of the Rejuvenate® Modular Hip System for primary total hip replacement (THR) with a cementless application in a consecutive series of patients who meet the eligibility criteria. Data from Secur-Fit™ HA monolithic femoral stem cases that are enrolled in the Trident® X3® Polyethylene Insert Study will be used as a historical control group.
Study Duration	• Minimum functional evaluation, assessment of health related quality of life (QOL) and radiographic follow-up of each primary THR case to 5 years • Enrollment period of 24 months • Completion of pain, satisfaction and survivorship patient questionnaire between 6 and 10 years • Approximate 12-year total duration
Study Center(s)	10 – 12
Hypothesis	The success rate, defined as freedom from femoral stem/neck construct revision/removal for any reason, for hips implanted with the Rejuvenate® Modular Hip System, is no worse than for hips implanted with the Secur-Fit™ HA monolithic femoral hip stem at 5 years postoperative.

Objectives	Primary: • To evaluate the success rate of cementless primary THR with the Rejuvenate® Modular Hip System as compared to the Secur-Fit™ HA monolithic femoral hip stem, through absence of revision at 5 years postoperative. Secondary: • To obtain natural preoperative biomechanical measurements and compare a preoperative plan to postoperative biomechanical measurements, within the Rejuvenate® Modular Hip System group. • To compare pain, function and health related QOL between the Rejuvenate® Modular Hip System group and the Secur-Fit™ HA monolithic femoral stem group. 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) • To review radiographic stability and complications between those implanted with the Rejuvenate® Modular Hip System and the Secur-Fit™ HA monolithic femoral stem group. Published complication rates with similar devices as well as complications related to modularity will be reviewed, as applicable.
Number of Subjects	240 cases

Diagnosis and Main Inclusion/Exclusion Criteria	Inclusions: A. Patient has signed an IRB approved, study specific Informed Patient Consent Form. B. Patient is a male or non-pregnant female age 18 years or older at time of study device implantation. C. Patient has primary diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD). D. Patient is a candidate for a primary cementless total hip replacement. E. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation. F. Patient's operative femur templates to Rejuvenate® Modular Stem size 7-12. Exclusions: G. Patient has a Body Mass Index (BMI) ≥ 40. H. Patient has an active or suspected latent infection in or about the affected hip joint at time of study device implantation. I. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device. J. 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. K. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days). L. Patient requires revision surgery of a previously implanted total hip replacement or hip fusion to the affected joint. M. Patient has a known sensitivity to device materials. N. Patient is a prisoner.

Study Device	**Rejuvenate® Modular Hip System** Required Components: • Rejuvenate® Modular Stem • Rejuvenate® Modular Neck The femoral components must be used in a cementless application.
Reference Therapy	Secur-Fit™ HA Monolithic Femoral Hip Stem
Ancillary Devices	Stryker acetabular components and femoral bearing heads must be used according to this study protocol. The following ancillary devices are permissible: • Stryker Trident® or Tritanium™ Primary acetabular shells, with or without screw fixation, as well as Stryker Restoration® ADM acetabular shells • Stryker alumina ceramic inserts (for use with Trident® acetabular shells) or X3® inserts • Stryker LFIT™ CoCr heads; delta ceramic heads; or alumina ceramic heads with adaptor sleeve

Statistical Methodology	Primary: The 90% confidence interval around the difference in success rate (Rejuvenate® Modular Hip System – Secur-Fit™ HA monolithic femoral stem) will be computed at 5 years postoperative. For the non-inferiority comparison, the lower bound of this 90% confidence interval will be compared with -5%. Secondary: • A t-test or Wilcoxon test will be used to compare the postoperative biomechanical measurements to a preoperative plan. • Independent group t-tests will also compare HHS, SF-12 and LEAS at applicable time points between the Rejuvenate® Modular Hip System and Secur-Fit™ HA monolithic femoral stem groups. In addition, a paired t-test will compare the results preoperatively with each postoperative evaluation within the Rejuvenate® Modular Hip System group. • The adverse event (AE) rates and 95% confidence intervals will be presented within the Rejuvenate® Modular Hip System group. A Fisher's exact test will be used to compare the AE rates between the Rejuvenate® Modular Hip System and the Secur-Fit™ HA groups, if appropriate. • Radiographic data will be summarized in table format.

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												
Preoperative Biomechanical Measurements	X												
Surgical Details		X											
Postoperative Functional Evaluation			X	X	X	X	X	X		Optional			Optional
Postoperative Biomechanical Measurements			X										
SF-12	X		X	X	X	X	X	X		Optional			Optional
LEAS	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 inclue 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.

Follow-up Questionnaire: The Follow-up Questionnaire is a short patient questionnaire intended to provide information on 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

Modular hip prostheses have been in clinical use since 1985. In a study of 216 anatomic cementless THRs (208 patients) with ceramic bearings and modular necks, followed for a minimum of 3 years, the authors affirm that the advantages of this method include its adaptability to a variety of anatomical conditions. From a clinical standpoint, all of the patients achieving long-term follow-up demonstrated improvement in pain, movement and walking. Radiographically, bone stability was observed in 98.8% of stems. A total of 99.4% of stems were osseointegrated and only one case showed osteolysis requiring revision of stem and cup after 2 years. This data supports the conclusion that neck modularity has not changed the survivorship of standard primary hip femoral components, while facilitating implantation in patients with varied anatomical conditions.[1]

A review by Spitzer[2] of a similar modular device's 20-year clinical history shows that the prosthesis has performed well in both primary and revision cases. The modular junction has survived with long-term clinical follow-up. The author argues that despite concerns regarding fretting and failure at the modular junction, mid to long-term follow-up indicates that these issues do not pose a significant concern. Furthermore, fixation by the proximal sleeve has proven reliable and durable, and loosening rates have been low, as evidenced by clinical data.[3]

Stryker is introducing a modular hip prosthesis, the Rejuvenate® Modular Hip System. The basic design of the Rejuvenate® Modular Hip System is similar to other total hip systems, both modular and monolithic, which are currently commercially distributed. The Rejuvenate® Modular Hip System's design features are based upon the previous success of Stryker's hydroxylapatite (HA) coated monolithic femoral components.

Table 1. Rejuvenate® Modular Hip System Design Features

Product	Identifying Features	Based upon Clinical History of the Following
Straight, Cementless Modular Stem	TMZF® Alloy Plasma Spray PureFix™ HA	Omnifit® HA Secur-Fit™ HA

The Omnifit® HA femoral component has long-term survivorship in a relatively young patient group, with a low mechanical failure rate compared to other fixation methods at similar lengths of follow-up. A total of 166 hips (146 patients) were followed for an interval of 15 to 18 years, with both femoral aseptic revision and mechanical failure rates at approximately 0.6%.[4] Omnifit® is considered Stryker's gold standard for proximal HA-coated femoral stems. The Rejuvenate® Modular Hip System is an updated version of the Omnifit®, modifying the C-taper trunnion and bulky neck geometry. These features are considered weaknesses of the Omnifit® design.

The Secur-Fit™ system, the historical control for this clinical study, was based on the geometry of the Omnifit® femoral stem. The Secur-Fit™ HA stem retains the Omnifit® geometry, normalized design and PureFix™ HA coating to further enhance initial stem stability and augment proximal load transfer. The Secur-Fit™ HA stem has a highly polished neck, decreasing the potential for polyethylene debris. Each implant maintains the same geometry, regardless of stem size, allowing the stems to more closely match natural anatomy.

In a clinical and radiographic review by Jaffe and Hawkins[5] of 215 THRs in which a monolithic, normalized, proportionalized, cemented femoral component was implanted, the design was reported to allow for more efficient force transmission between prosthesis, cement and bone and to lessen failure rates at these interfaces. Overall, the study showed an aseptic failure loosening rate of 3.9% at 15 years for the stem. These results were favorable when compared with other first generation and second generation stems at similar follow-up.[6] Although the Rejuvenate® Modular Hip System is intended for cementless application, the findings by Jaffe and Hawkins[7] focus on a normalized femoral component. As with the femoral stem studied, the Rejuvenate® Modular Stem includes a normalized pattern on the anterior and posterior aspects of the proximal end of the stem, facilitating load transmission in the proximal region of the femur.

The Secur-Fit™ system is the direct predecessor for the Rejuvenate® Modular Hip System. The Rejuvenate® Modular Hip System introduces the concept of modularity, offering the surgeon additional intraoperative flexibility. The mixing and matching of components, as described further in Section 6, Device Description, allows the surgeon to choose the best anatomical fit for the patient. The Rejuvenate® Modular Hip System permits the matching of a proximal femoral neck in different lengths, angles and version, with different sizes of distal stems.

This clinical study is necessary to compare the success of the Rejuvenate® Modular Hip System to the reported success of its monolithic predecessor. The objective of the study is to show that neck modularity has not changed the survivorship of standard primary hip femoral components.

1.2 Investigational Device

The Rejuvenate® Modular Hip System is fabricated from TMZF® alloy and features the PureFix™ HA fixation philosophy. The stem is built upon the design features and clinical history of the existing Omnifit® and Secur-Fit™ Stryker femoral stems. The device provides better patient matching by allowing for interchange of the femoral neck angle, femoral neck length, version and femoral head offset. The Rejuvenate® Modular Hip System has a modular neck, allowing for 127°, 132° and 130° femoral neck angles. The 130° modular neck is only available in the 16° version option. Four femoral neck lengths are available, ranging from 30 mm to 42 mm, in 4 mm increments. Possible overall neck lengths range from 26 mm to 46 mm, utilizing V40 +/- 4 mm femoral heads.

The Rejuvenate® Modular Hip System is intended for use in a cementless application. It is designed to address the need for greater accuracy in reproducing offset, leg length and femoral neck version, as well as optimize range of motion (ROM) for primary hip patients. Data in support of these marketing claims will be collected in the Rejuvenate® Modular Hip System Outcomes Study.

The Rejuvenate® Modular Hip System is cleared for use as follows:

- FDA 510(k) K071082, original submission for sizes 7, 8, 9 and 10
- FDA 510(k) K081044, line extension for compatability between the size 9 stem and the 42 mm neck
- FDA 510(k) K092561, for use with up to 46 mm of total neck length

1.3 Preclinical Data

The following bench tests were conducted on the Rejuvenate® Modular Hip System:

Description of the test	Report ID
Mod. ISO-Neck Fatigue	– RD-07-029
ISO 7206-4 Distal Fixation Model	– RD-07-028
Fretting Size 7	– RD-07-054
Fretting Size 10	– RD-07-100
Flexion	– RD-07-101
Revision	– RD-07-056
Pull-off Strength/Disassembly	– RD-07-055

Copies of all test reports are available at Stryker Orthopaedics.

1.4 Clinical Data to Date

A limited number of evaluation instrument sets and implants have been distributed in the United States to date. Anecdotal feedback from the centers has been positive. This study is the first prospective data collection on the Rejuvenate® Modular Hip System.

2 Study Objectives

2.1 Efficacy

2.1.1 Primary

The primary objective of this study will be to evaluate the success rate of cementless primary THR with the Rejuvenate® Modular Hip System, as compared to the Secur-Fit™ HA monolithic femoral hip stem, a historical control. Success will be defined as absence of femoral stem/neck construct revision/removal for any reason at 5 years postoperative. It is expected that the survivorship of the Rejuvenate® Modular Hip

System group will be non-inferior to the survivorship reported for Secur-Fit™ HA monolithic femoral hip stem cases enrolled in the Trident® X3® Polyethylene Insert Study.

2.1.2 Secondary

The secondary objectives of this study will be to measure natural preoperative biomechanical measurements for creation of a preoperative plan, and compare to postoperative biomechanical measurements, within the Rejuvenate® Modular Hip System group. It is expected that the postoperative measurements at the 6-week interval will be similar to the preoperative plan.

Additionally, pain, function and health-related QOL between the Rejuvenate® Modular Hip System group and the Secur-Fit™ HA monolithic femoral hip stem group will be compared at postoperative time points. It is expected that the HHS, SF-12 and LEAS outcomes in the study group will be non-inferior to the historical control.

Lastly, radiographic stability and complications between those implanted with the Rejuvenate® Modular Hip System and the Secur-Fit™ HA monolithic femoral stem group will be reviewed. Published complication rates with similar devices as well as complications related to modularity will be reviewed, as applicable.

Clinical Outcomes:

Clinical outcomes will be evaluated via 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 back in for these optional visits.

Patient Outcomes:

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. 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. Additional patient outcomes data 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. A questionnaire

for patient completion, intended to provide information on patient satisfaction, pain and whether or not there have been any revisions or removals of the study device since the last follow-up visit, is required at the 6, 7, 8, 9 and 10-year visits.

Radiographic Outcomes:

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 views allow for observations of any conditions involving the sacral wings, iliac bones, ischium, pubis as well as the femoral head and neck. These views additionally display the critical relationship between the femoral neck's longitudinal axis and the femoral shaft's longitudinal axis for identification of displacement in the event of a femoral neck fracture. The lateral view allows for evaluation of the entire hip joint as well as specifically the femoral head, neck and proximal shaft.[8] 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 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; analysis of the acetabular component will employ three zones (Zone 1 – Zone 3) in the AP views.[9,10] Numerous parameters will be reviewed by zone, including radiolucency, hypertrophy, and condensation. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width is defined as radiolucency present.

Subsidence, migration and fixation will also be assessed. Subsidence is defined as settling of the prosthetic component in bone, and is related to the distance between fixed bony landmarks and the prosthesis.

Biomechanical Measurements:

Preoperatively, study radiographs will be taken by each investigator. From these radiographs, each investigator will determine natural measurements and provide a detailed picture of each patient's level of deformity, as follows.

- Leg length discrepancy (centimeters)
  - Measurement of leg length discrepancy should be determined from the AP pelvis radiograph by drawing lines across both pelvic teardrops to meet both femurs. These lines are to be used as the main reference lines for measuring the distance to the top of each lesser trochanter.[11] The difference between these distances is the value of leg length discrepancy.
- Natural femoral offset (millimeters)
  - Femoral offset should be determined by measuring the perpendicular distance from the center of the femoral head to the axis along the length of the femur.[12]
- Natural femoral neck angle (degrees)
  - Femoral neck angle is the angle between the long axes of the femoral neck and femoral shaft.[13]
- Qualitative assessment of natural femoral version (Retroverted, Neutral, Anteverted)
  - Proximal femoral version reflects the relationship of the axis of the femoral neck to the transcondylar axis of the distal femur.[14] Qualitative determination of whether natural femoral version is retroverted, anteverted or in a state of neutral version should be made from the lateral radiograph.

The investigator at each center will create a preoperative biomechanical measurement plan for each case from templating, reflecting desired postoperative measurements and the component sizes, angles and offsets that will be used to achieve these measurements. All component sizes should be corrected for magnification (if any) prior to data collection on the study Case Report Form (CRF). This may be accomplished by utilizing an external radiographic marker of known dimension prior to taking the preoperative radiograph.[15]

Preoperative Distance from Planned Center of Rotation

- Vertical distance from the anatomic hip center to the planned center of rotation of the hip (millimeters)
- Horizontal distance from the anatomic hip center to the planned center of rotation of the hip (millimeters)

Components to be Used

- Acetabular cup size
- Femoral neck angle [127°, 132°, 130° (16° version option only)]
- Femoral neck length (millimeters)
- Femoral head size
- Femoral head offset
- Femoral stem size*
- Femoral version (0°, ±8°, ±16°)

*The Rejuvenate® Modular Stem will be available in sizes 7, 8, 9, 10, 11 and 12. The Rejuvenate® Monolithic Stem will be available in sizes 4, 5 and 6; however, **the Rejuvenate® Monolithic Stem may not be used according to this protocol**. Patients requiring a femoral stem in size 4, 5 or 6 should not be enrolled into the study. Investigators should template the femoral stem size to be used prior to completing the Inclusion/Exclusion CRF for enrollment into the study.

Additional Planned Measurements

- Amount of leg length to be restored (centimeters)
    - Measurement of leg length discrepancy should be determined from the AP pelvis radiograph by drawing lines across both pelvic teardrops to meet both femurs. These lines are to be used as the main reference lines for then measuring the distance to the top of each lesser trochanters.[16] The difference between these distances is the value of leg length discrepancy. From this value, the investigator will determine the amount of leg length he/she plans to restore.
- Femoral offset to be achieved (millimeters)
- Qualitative assessment of postoperative planned femoral version (Retroverted, Neutral, Anteverted)

A postoperative check of biomechanical measurements will be performed by the investigator at each site from the 6-week radiographs to confirm the degree to which the

preoperative plan was achieved. If an AE for instability exists, the postoperative check will be taken again at applicable postoperative intervals to confirm whether or not changes have occurred.

Postoperative Distance from Planned Center of Rotation

- Vertical distance from the postoperative hip center to the planned preoperative center of rotation of the hip (millimeters)
- Horizontal distance from the postoperative hip center to the planned preoperative center of rotation of the hip (millimeters)

Additional Postoperative Measurements

- Leg length discrepancy (centimeters)
- Final femoral offset (millimeters)
- Final femoral neck angle used [127°, 132°, 130° (16° version option only)]
- Qualitative assessment of replaced femoral version (Retroverted, Neutral, Anteverted)

These postoperative values will be compared to the preoperative plan to evaluate the degree of patient matching achieved with the Rejuvenate® Modular Hip System.

Component sizes used intraoperatively will be automatically determined from catalog numbers provided on the Surgical Details CRF.

Biomechanical measurements are outlined in Appendix B.

2.2 Safety

All operative site events as well as all serious adverse events (SAEs), excluding elective procedures, will be collected and compared to the historical control group and to published data. It is expected that the AE rates reported for the Rejuvenate® Modular Hip System will be comparable to those reported in the literature for similar modular stems and for the historical control group. For incidence of femoral neck fracture, a complication related to modularity, it is expected that rates reported for the Rejuvenate® Modular Hip System will be comparable to those reported in the literature for similar modular stems. 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 10 to 12 centers in the United States. The enrollment goal ranges from 20 to 24 THA cases per center, utilizing the Rejuvenate® Modular Hip System. The enrollment goal range is dependent upon the number of participating centers. Although a range 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 IRB approval. Non-compliance of a study center may result in termination of the center's participation in the study.

3.3 Number of Subjects

A total of 240 cases will be enrolled in this study. All cases will receive the Rejuvenate® Modular Hip System. Additionally, only the following ancillary devices may be used according to this study protocol:

- Stryker Trident® or Tritanium™ Primary acetabular shells, with or without screw fixation, as well as Stryker Restoration® ADM acetabular shells
- Stryker alumina ceramic inserts (for use with Trident® acetabular shells) or X3® inserts
- Stryker LFIT™ CoCr heads; delta ceramic heads; or alumina ceramic heads with adapter sleeve

The Rejuvenate® Modular Hip System is described in detail in Section 6 of this protocol, Device Description.

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. Functional evaluation,

assessment of health related QOL and radiographic follow-up of each primary THR case to 5 years is required. Completion of the pain, satisfaction and survivorship patient questionnaire between 6 and 10 years is also required, with optional in-office visits at 7 and 10 years for collection of additional functional, QOL and radiographic data.

To allow for a learning curve with the use of the system, enrollment of cases into the study will commence when three cases have been completed at the center using the Rejuvenate® Modular Hip System.

4 Eligibility

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

4.1 Inclusion Criteria

A. Patient has signed an IRB approved, study specific Informed Patient Consent Form.
B. Patient is a male or non-pregnant female age 18 years or older at time of study device implantation.
C. Patient has primary diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
D. Patient is a candidate for a primary cementless total hip replacement.
E. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.
F. Patient's operative femur templates to Rejuvenate® Modular Stem size 7-12.

4.2 *Exclusion Criteria*

G. Patient has a Body Mass Index (BMI) ≥ 40.
H. Patient has an active infection within the affected hip joint.
I. Patient requires revision surgery of a previously implanted total hip arthroplasty or hip fusion to the affected joint.
J. Patient has a neuromuscular or neurosensory deficiency, which limits ability to evaluate the safety and efficacy of the device.
K. Patient is diagnosed with systemic disease or current life threatening illness and is not able to carry on normal activities of daily life (e.g. Paget's disease, renal osteodystrophy, rheumatoid arthritis).
L. Patient is immunologically suppressed or receiving chronic steroids in excess of normal physiological requirements (e.g. > 30 days).
M. Patient has a known sensitivity to device materials.
N. Patient is a prisoner.

5 Subject Enrollment

5.1 *Treatment Assignment*

All subjects enrolled in this study will be assigned to receive the Rejuvenate® Modular Hip System.

5.2 *Randomization*

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

6 Device Description

6.1 *Study Device*

The Rejuvenate® Modular Hip System has been cleared for marketing in the United States, and, therefore, this study is considered a post-market assessment. All cases in this study will receive the Rejuvenate® Modular Hip System, consisting of the Rejuvenate® Modular Stem and the

Rejuvenate® Modular Neck. Additionally, only the following **Stryker compatible** ancillary devices may be used, according to this study protocol:

- Stryker Trident® or Tritanium™ Primary acetabular shells, with or without screw fixation, as well as Stryker Restoration® ADM acetabular shells
- Stryker alumina ceramic inserts (for use with Trident® acetabular shells) or X3® inserts
- Stryker LFIT™ CoCr heads; delta ceramic heads; or alumina ceramic heads with adapter sleeve

Device Description:

The Rejuvenate® Modular Hip System consists of a modular stem and a modular neck. It is similar to other modular and monolithic hip systems currently distributed. It is intended for cementless, press-fit application and is designed for use with currently available Stryker femoral heads. A description of the Rejuvenate® Modular Hip System components and compatible femoral heads follows. Stryker acetabular components compatible with the chosen Stryker femoral heads must be used, according to this study protocol. Appendix C gives an overview of all protocol-specified components.

Modular Stem:

The modular stem design is based on the Secur-Fit™ system. The Rejuvenate® Modular Hip System includes a straight stem with a normalization pattern on the anterior and posterior aspects of the proximal end of the stem to facilitate press-fit stability and load transmission in the proximal region of the femur. The stem has an internal opening which mates with the modular neck via an oblong Morse-type taper. The drawing below depicts the stem design.

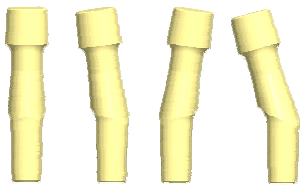
The Rejuvenate® Modular Stem will be available in sizes 7, 8, 9, 10, 11 and 12. The Rejuvenate® Monolithic Stem will be available in sizes 4, 5 and 6; however, **the Rejuvenate® Monolithic Stem may not be used according to this protocol**. Patients requiring a femoral stem in size 4, 5 or 6 should not be enrolled into the study. Investigators should template the femoral stem size to be used prior to completing the Inclusion/Exclusion CRF for enrollment into the study.

The hip stems will be fabricated from TMZF® (TiMoZrFe) alloy. The Titanium plasma spray coating is Commercially Pure (CP) Titanium and the coating will be hydroxylapatite powder (Pure-Fix™ HA). The HA coating thickness will be between 40 – 70 μm.
The catalog numbers for the Rejuvenate® Modular Stem permissible according to this study protocol will be in the following format, where 'XX' varies by size:

SPT-XX0000S

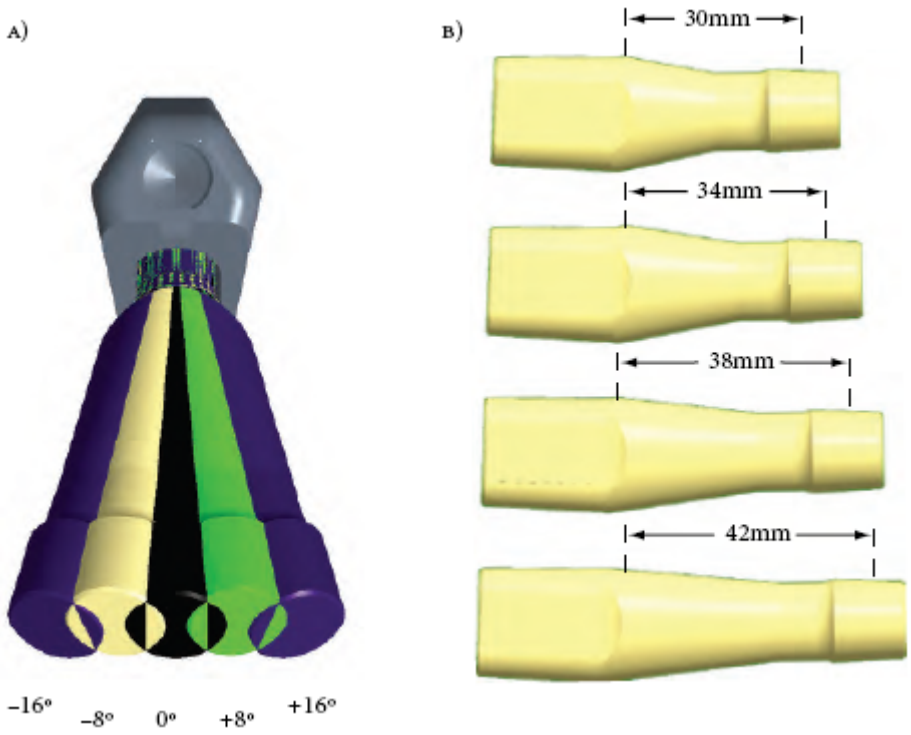
Modular Neck:

The modular necks are manufactured from CoCrMo alloy and are available in 16 options in various lengths ranging from 30 mm to 42 mm and angles of 0°, 8° and 16° version. All modular necks, except for the 16° version, have varus and valgus options of 127° and 132° neck angles. The 16° version modular neck has a single neck-angle option of 130°. The drawing below shows the various styles of necks.

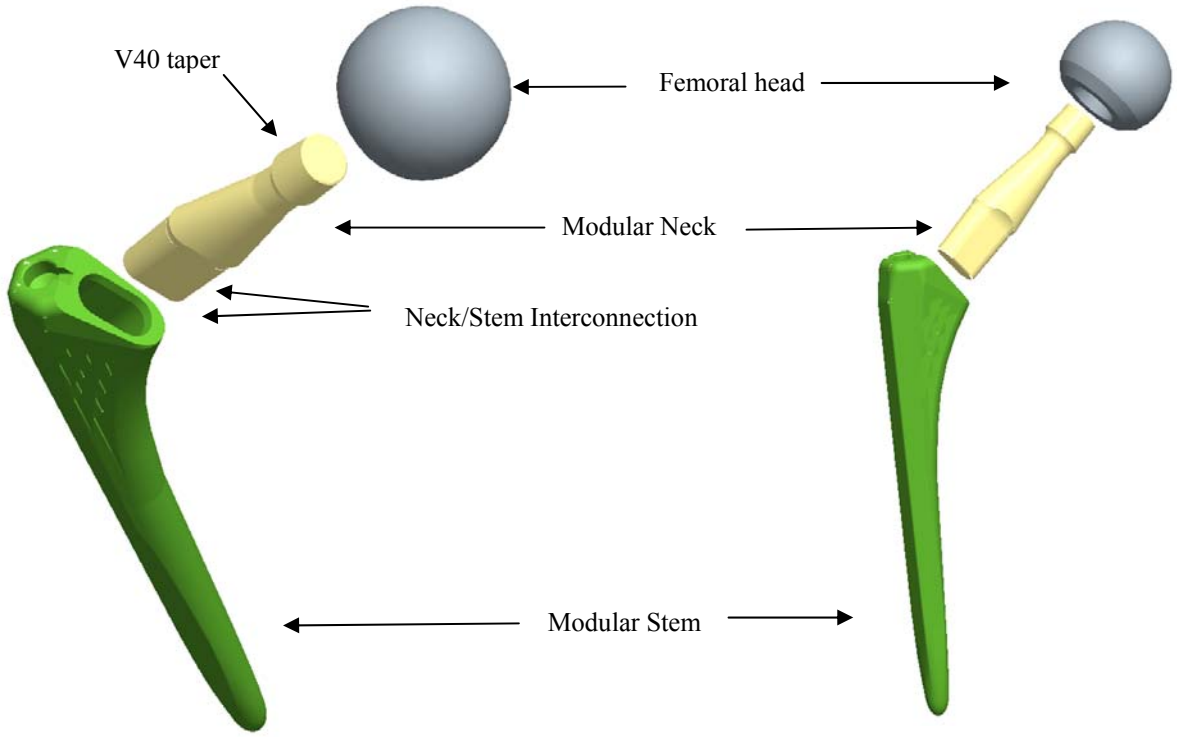


The catalog numbers for the Rejuvenate® Modular Necks permissible according to this study protocol are listed in Appendix C.

Each modular neck fits into a given stem to create two different constructs.



The neck has two different tapers for mechanically locking the components: stem to neck interconnection and neck to modular head interconnection. Following is a drawing illustrating the interconnections between the three components.



Modular Heads:

The modular neck is designed for use with Stryker V40 femoral heads with different offsets, or C-Taper Alumina heads when used with the adaptor sleeve. Biolox® Delta Universal Taper Heads and sleeves may also be used. The offset of the femoral head will be independent of the choice of femoral stem body size. Total head/neck length equals head offset plus neck length.

Tables 2 and 3 list the permissible stem/neck/head combinations.

Table 2. Rejuvenate® Modular Hip System Achieved Neck Length/Stem Compatibility

Version	Stem Size					
	7	8	9	10	11	12
0°	46*	46*	46*	46*	46*	46*
8°	46*	46*	46*	46*	46*	46*
16°	38	38	42	46*	46*	46*

* Achieved only by combining a Modular Neck with a head offset greater than +0mm.

Table 3. Rejuvenate® Modular Hip System Head/Neck Combinations

Head and Neck Combination*

Modular Neck Implant	Femoral Head Offsets*											
	-5mm	-4mm	-2.7mm	-2.5mm	+0mm	+2.5mm	+3mm	+4mm	+5mm	+7.5mm	+8mm	+10mm	+12mm
30mm	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔†	✔†
34mm	✔	✔	✔	✔	✔	✔	✔	✔	✔†	✔†	✔†	✔†‡	✔†‡
38mm	✔	✔	✔	✔	✔	✔†	✔†	✔†	✔†‡	✔†‡	✔†‡		
42mm	✔	✔	✔†	✔†	✔†	✔†‡	✔†‡	✔†‡					

† 16° version not compatible with sizes 7 & 8 ‡ 16° version not compatible with size 9

* Not all offsets are available in all materials or all diameters. The table includes C-taper and V40 offset head options. Use of the C-taper head requires the assembly of a Titanium Adapter Sleeve (17-0000E) to convert the V40 stem trunnion to C-taper.

Ancillary Devices:

Only Stryker Trident® or Tritanium™ Primary acetabular shells, Stryker Restoration® ADM acetabular shells, Stryker alumina ceramic (for use with Trident® acetabular shells) or X3® inserts, and Stryker compatible femoral heads/sleeves, as described previously, may be used as ancillary devices according to this study protocol.

X3® polyethylene is a highly cross-linked polyethylene manufactured through a proprietary process where the polyethylene receives 30 kiloGrays of gamma radiation, which generates free radicals and cross-linking in ultra high molecular weight polyethylene (UHMWPE) prior to machining. The polyethylene is then annealed below melting point to promote cross-linking and maintains mechanical strength[a], crystallinity[b], and density[c]. This also stabilizes the free radicals[d]. This process is repeated twice.

[a] X3® UHMWPE maintains mechanical properties for Tensile Yield Strength and Ultimate Tensile Strength of N_2Vac® gamma sterilized UHMWPE as measured by ASTM D638. Tensile Yield Strength was 23.2 ±

6.2 Device Retrieval Process

Stryker Orthopaedics will retrieve any Rejuvenate® Modular Hip System components and/or adjacent tissues for analysis to help characterize potential device-related complications. In the event that any portion of the Rejuvenate® Modular Hip System is removed from a study subject, the outlined procedure should be followed.

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. The SC or an identified field representative will retrieve the device and place it in the retrieval container.
4. The SC or an identified Stryker representative will complete a Product Experience Report (PER).
5. 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.

0.4 MPa and 23.5 ± 0.3 MPa for N_2Vac® UHMWPE and X3® UHMWPE, respectively. Ultimate Tensile Strength was 54.8 ± 2.5 MPa and 56.7 ± 2.1 MPa for N_2Vac® UHMWPE and X3® UHMWPE, respectively.

[b] X3® UHMWPE has similar crystalline and lamellar structure as N_2Vac® gamma sterilized UHMWPE as measured by Small Angle X-ray Scattering (SAXS) and Differential Scanning Calorimetry (DSC) analysis. DSC determined crystallinity was 61.3 ± 0.8% and 61.7 ± 0.6% for N_2Vac® UHMWPE and X3® UHMWPE, respectively. Lamellar crystal thickness was 23.0 and 23.6 nanometers for N_2Vac® UHMWPE and X3® UHMWPE, respectively.

[c] X3® UHMWPE increases cross-link density over N_2Vac® gamma sterilized UHMWPE by 87%, as measured by swell ratio, per ASTM F2214. Cross-link density, as measured by swell ratio, was 0.08 ± 0.00 mol/dl and 0.15 ± 0.01 mol/dl for N_2Vac® UHMWPE and X3® UHMWPE, respectively.

[d] 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 N_2Vac® gamma sterilized UHMWPE.

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 approved study consent form prior to participating in any study related activities. Consent must be obtained within four months of surgery.

Once the subject has been consented, preoperative data will be collected including: demographics, medical history, HHS, AP hip, AP pelvis and lateral radiographs, SF-12, and LEAS.

Additionally, the investigator will measure the following from preoperative radiographs, including:

- Leg length discrepancy (millimeters)
- Natural femoral offset (millimeters)
- Natural femoral neck angle (degrees)
- Qualitative assessment of natural femoral version (Retroverted, Neutral, Anteverted)

The investigator will then proceed with a preoperative plan from templating, reflecting desired postoperative measurements and the component sizes, angles, and offsets that will be used to achieve the following measurements:

Preoperative Distance from Planned Center of Rotation

- Vertical distance from the anatomic hip center to the planned center of rotation of the hip (millimeters)
- Horizontal distance from the anatomic hip center to the planned center of rotation of the hip (millimeters)

Components to be Used

- Acetabular cup size
- Femoral neck angle [127°, 132°, 130° (The 130° neck angle is only available in 16° of version.)]
- Femoral neck length (millimeters)
- Femoral head size
- Femoral head offset
- Femoral stem size*
- Femoral version (0°, ±8°, ±16°)

*The Rejuvenate® Modular Stem will be available in sizes 7, 8, 9, 10, 11 and 12. The Rejuvenate® Monolithic Stem will be available in sizes 4, 5 and 6; however, **the Rejuvenate® Monolithic Stem may not be used according to this protocol**. Patients requiring a femoral stem in size 4, 5 or 6 should not be enrolled into the study. Investigators should template the femoral stem size to be used prior to completing the Inclusion/Exclusion CRF for enrollment into the study.

Additional Planned Measurements

- Amount of leg length to be restored (millimeters)
- Femoral offset to be achieved (millimeters)
- Qualitative assessment of planned postoperative femoral version (Retroverted, Neutral, Anteverted)

All preoperative data must be collected within 4 months of the scheduled date of surgery, with the exception of radiographs, acceptable within 1 year of 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

Clinical data will be collected via office visit by the investigator at the 6-week postoperative interval. Tools for postoperative evaluation will be the HHS, AP hip, AP pelvis and lateral radiographs.

Patient outcomes data will also be collected via patient questionnaires. At the 6-week follow-up visit, the SF-12 and LEAS are required.

All clinical data, radiographs, and patient outcomes data must be collected within ± 3 weeks of the 6-week postoperative milestone date.

Additionally, each investigator will perform a postoperative check of biomechanical measurements from the 6-week radiographs:

Postoperative Distance from Planned Center of Rotation

- Vertical distance from the postoperative hip center to the planned preoperative center of rotation of the hip (millimeters)
- Horizontal distance from the postoperative hip center to the planned preoperative center of rotation of the hip (millimeters)

Additional Postoperative Measurements

- Leg length discrepancy (millimeters)
- Final femoral offset (millimeters)
- Final femoral neck angle used [127°, 132°, 130° (The 130° neck angle is only available in 16° of version.)]
- Qualitative assessment of replaced femoral version (Retroverted, Neutral, Anteverted)

These postoperative values will be compared to the preoperative plan to evaluate the degree of patient matching achieved with the Rejuvenate® Modular Hip System.

Component sizes used intraoperatively will be automatically determined from catalog numbers provided on the Surgical Details CRF.

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 hip, AP pelvis and lateral radiographs.

Patient outcomes data will also be collected via patient questionnaires. At each of the 1-year, 2-year, 3-year, 4-year and 5-year follow-up visits, the SF-12 and LEAS are required.

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

The initial phase of the study will conclude after the 5-year follow-up visit but, at investigational sites that choose to continue collecting clinical, patient outcome and radiographic data, subjects will be evaluated again at 7 and 10 years after surgery.

In addition, 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 patient telephone interview or by the patient either at home or during a clinic visit. The questionnaire will be used to obtain the following information, at a minimum:

- Patient satisfaction with the hip replacement
- Presence of any pain in the study hip
- Any surgeries perfomed on the study hip

The questionnaire will also provide information on any revisions and enable calculation of the Kaplan-Meier survival curve.

For 7 through 10 years, the window is ± 4 months of the respective anniversary date.

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:

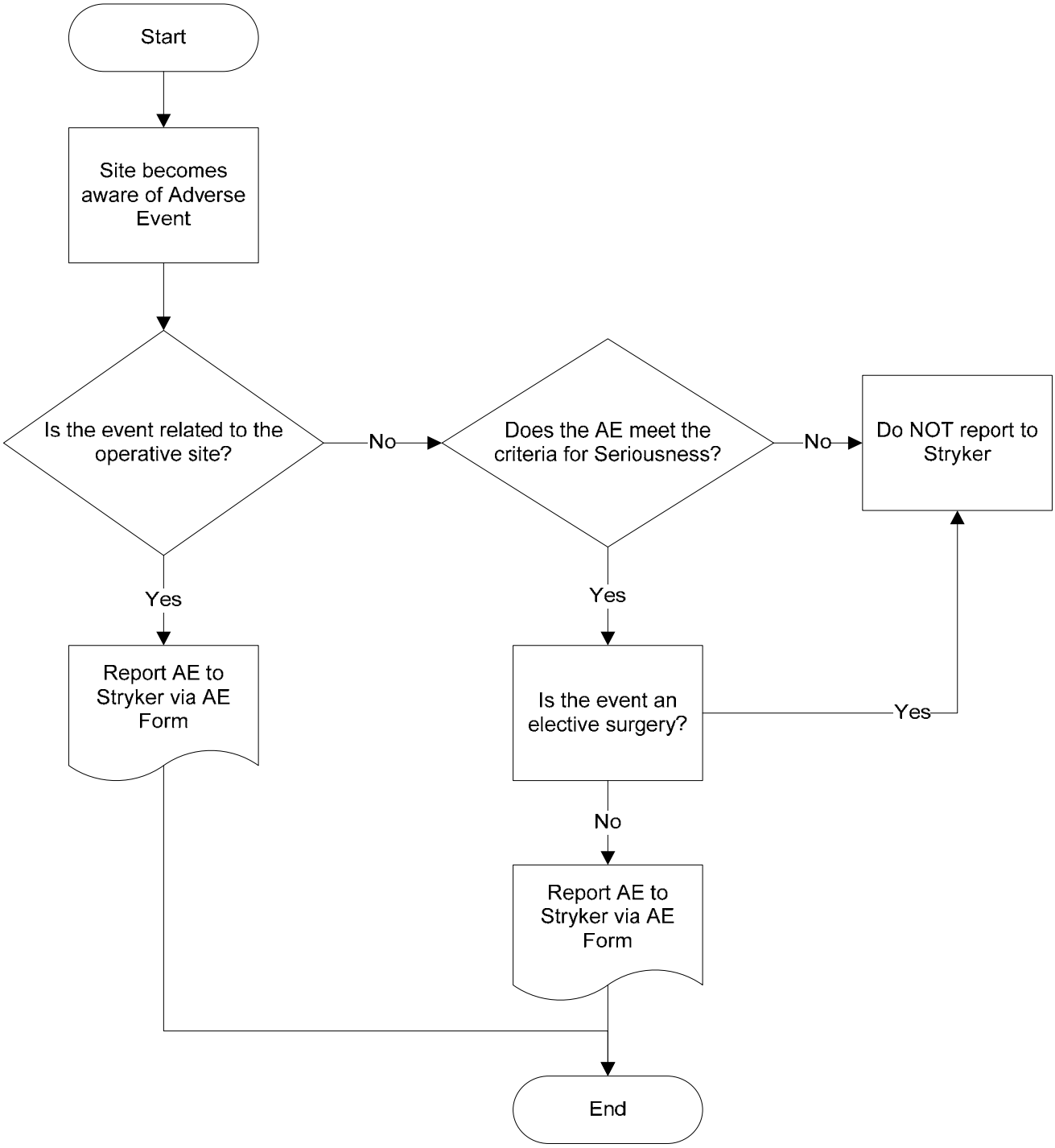
- Contralateral THR
- Total Knee Replacement
- Rotator Cuff Surgery
- Cataract Surgery

Such events will not be captured on the AE CRF 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 (as well as at optional 7 and 10-year 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.

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

Figure 1

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 CRF. 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 CRF. 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 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 Fax Notification by Investigator

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

- Events which meet the definition of serious
    - This does not include elective procedures, as these events are not reportable according to this study protocol.
- Events which are deemed to be "related to" or "uncertain" in regard to relation to the device

An AE CRF must be completed by the investigator and faxed to Stryker within 24 hours. The investigator will keep a copy of this AE CRF on file at the study center and submit the hard copy as per CRF data submission procedures. Report SAEs to one of the following study personnel:

Christina M. Hawley	Michael Howard
Phone: 858-344-9792	Phone: 201-831-5807
Fax: 201-831-6454	Fax: 201-831-6454
christina.hawley@stryker.com	michael.howard@stryker.com

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

• Subject number • A description of the event • Date of onset • Current status	• Whether 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 Ethics Committee (EC) or Institutional Review Board (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 will be femoral stem/neck construct revision/removal for any reason.

9.1.2 Secondary Efficacy Parameters

The secondary efficacy parameters include:

- Biomechanical measurement change from preoperative plan at 6-week visit
- HHS at each visit
- SF-12 scores at each visit
- LEAS at each visit

9.1.3 Primary Efficacy Hypothesis

The primary hypothesis to be tested will be that the proportion of cases without femoral stem/neck construct revision/removal is no worse for patients with the Rejuvenate® Modular Hip System than for cases with the Secur-Fit™ HA monolithic femoral stem at 5 years. A non-inferiority comparison with a one-sided alpha set at 0.05, power of 80% and delta of 7% will be performed. That is, the following hypothesis will be tested:

H_0: $P1 < P2 - \delta$ vs. H_a: $P1 > P2 - \delta$

where P1 and P2 are the proportions of cases without femoral stem/neck construct revision/removal for any reason for the Rejuvenate® Modular Hip System group and the Secur-Fit™ HA monolithic femoral stem control group, respectively and δ=7%.

9.1.4 Primary Efficacy Analysis

A case success is defined as no incidence of femoral stem/neck construct revision/removal. The 90% confidence interval around the difference in success rate (Rejuvenate® Modular Hip System – Secur-Fit™ HA monolithic femoral stem) will be computed at 5 years postoperative. For the non-inferiority comparison, the lower bound of this 90% confidence interval will be compared with -5%. If it is greater than -5%, non-inferiority is supported. In addition, if it is greater than 0%, superiority is supported. The Kaplan-Meier survival curve will also be displayed using SAS/PROC LIFETEST.

9.1.5 Secondary Efficacy Analysis

A two-sided 0.05 alpha level will be used.

For comparison of biomechanical measurements between a preoperative plan and postoperative measurements within the Rejuvenate® Modular Hip System group, a t-test or Wilcoxon test will be used.

Independent group t-tests will compare HHS, SF-12 and LEAS at each time point between the Rejuvenate® Modular Hip System and Secur-Fit™ HA monolithic femoral stem groups. In addition, a paired t-test will compare the results preoperatively with each postoperative evaluation within the Rejuvenate® Modular Hip System group.

9.2 Safety Parameters

9.2.1 Safety Parameters

Safety parameters will include all AEs reported for each group, radiographic stability at each postoperative visit and revision rates.

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. In addition, a

Fisher's exact test will be used to compare the AE rates between the Rejuvenate® Modular Hip System and the Secur-Fit™ HA groups or cohorts, if appropriate.

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

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 will be computed. If appropriate, the data will be presented by the Rejuvenate® Modular Hip System and the Secur-Fit™ HA groups.

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

A survival analysis for revision/removal of the modular femoral stem/neck construct will be performed.

9.4.2 Sample Size Calculation

Given an estimated revision rate for both groups at 2.5% and a non-inferiority margin of 5%, with a one-sided alpha of 0.05 and 80% power, a total of 147 cases per group are required to reject the null hypothesis that the revision rate for Rejuvenate® Modular Hip System cases is 5% greater than for Secur-Fit™ HA monolithic femoral stem cases. In order to control for a 20% drop-out rate, 183 cases per group are required.

A total of 240 cases received the Secur-Fit™ HA femoral stem in the Trident® X3® Polyethylene Insert Study, a historical control. Therefore, although only 183 cases are needed for statistical power, 240 cases will be enrolled in the Rejuvenate® Modular Hip System Outcomes Study.

9.4.3 Interim Analyses and early Stopping Considerations

No interim analysis is planned.

9.4.4 Patient Populations

Modified Intent-to-Treat (ITT) Population: The study population for analysis will include all subjects who receive the Rejuvenate® Modular Hip System or the Secur-Fit™ HA monolithic femoral stem. This does not include cases censored from analysis for a reason that may have a significant impact on outcome.

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

Per Protocol Population: The study population will include all subjects who receive the Rejuvenate® Modular Hip System or the Secur-Fit™ HA monolithic femoral stem. This does not include cases that have major protocol violations including the violation of entry criteria. In order for cases to be included in the per protocol population, the data required for analysis of a specific parameter must be present. Any data of secondary variables will be included, where possible.

The primary efficacy analyses and safety analysis will be based on the modified ITT population; the secondary efficacy analyses will be based on the per protocol population.

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. See

Appendix D for samples of study advertisements. All handouts, brochures, advertisements, etc. must be approved by the IRB 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 a consent form describing this study and providing sufficient information for them to make an informed decision about their participation. The informed consent must contain all elements required by the FDA under 21 CFR Part 50, in addition to any other elements required by state, local and institutional policies. See Appendix E for a copy of the Model Informed Patient Consent. This consent form will be submitted with the protocol for review and approval by the IRB 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 approved 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 consent's signature page in addition to a note in the patient medical records indicating the date that consent was obtained. The investigator-designated research professional obtaining the consent must also sign this consent form. The patient or their legal representative should receive a signed copy of the consent according to GCP guidelines.

The procedure for obtaining informed consent is outlined below:

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

10.3 Early Withdrawal of Subjects

When and How to Withdraw Subjects

In the event that the subject is discontinued by the investigative 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 CRF 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 CRF 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:

- Rejuvenate® Modular Stem
- Rejuvenate® Modular Neck
- Stryker Trident® or Tritanium™ Primary acetabular shells, with or without screw fixation, as well as Stryker Restoration® ADM acetabular shells
- Stryker alumina ceramic inserts (for use with Trident® acetabular shells) or X3® inserts
- Stryker LFIT™ CoCr heads; delta ceramic heads; or alumina ceramic heads with adapter sleeve

Revision or removal of the Rejuvenate® Modular stem/neck construct constitutes a failure and study termination for the subject.

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

If acetabular shell and insert 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 CRF 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 CRF 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 CRF will be completed.

11 Data Management

11.1 Database

Data will be collected at each center and sent to Stryker for entry into a database which will reside at Stryker. Subject data will be collected, processed and monitored according to the protocol schedule by Stryker or Stryker representatives. Draft CRFs are provided in Appendix F.

11.2 Confidentiality

This study 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 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 will not be 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 CRFs 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 Case Report Forms

The study CRFs are the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D." If the item is not applicable to the individual case, write "N/A." All entries should be printed legibly in blue or black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. **Do not erase or white out errors**. For clarification of illegible or uncertain entries, print the clarification above the item, initial and date it.

For specific instructions on CRF completion, please consult the Guide to Case Report Forms provided under separate cover. CRFs should be completed, signed by the investigator and returned to Stryker within 2 weeks of the evaluation date.

11.5 Data Clarification Requests

If errors or omissions are noted by Stryker upon receipt of the forms, a data clarification form (DCF) or data clarification request (DCR) will be sent to the center for clarification. Clarifications should be answered in a clear and comprehensible manner. If the clarification requires a change to data captured on a CRF, the CRF should be modified accordingly. The clarification should clearly document changes, independent of the CRF to which it refers. DCFs and DCRs must be signed and dated by the investigator. Completed clarifications should be returned to Stryker within 2 weeks of receipt. Modified CRFs need not be included in conjunction to answered DCFs and 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 CRFs/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 device under study has been cleared for marketing by the FDA and will be used according to its labeling. Assessment involves questionnaires, patient and physician assessments, and routine radiographs. The information collected will be kept confidential and will comply with the HIPAA.

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

also 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.

If bone screws are used, appropriate selection of bone screw length and location is essential to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.

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*

The safety objective will compare the Rejuvenate® Modular Hip System complication rates to published rates. Table 4 on the following page lists expected rates for primary THA, averaged from Stryker clinical studies as well as from published results.

Table 4. Primary THA Expected Complication Rates

Event	SO Clinical Studies*	Primary THA
Related to Surgery		
Femoral crack/fracture	3.78%	1.37%[17], 4.0%[18]
Trochanteric crack/fracture	0.54%	3-17.6% range for all periprosthetic fractures[19]
Acetabular crack/fracture	0.30%	(see above)
Superficial wound infection	0.94%	1.0%[20]
Deep joint infection	0.54%	2.05%[21], 0.2%[22]
Peroneal nerve palsy	0.44%	0-3.0%[23]
Related to Implant		
Femoral stem fracture	0.07%	2.63%[24]
Femoral head fracture	0.0%	1.27%[25], 1.87%[26]
Acetabular shell fracture	0.0%	Not available
Acetabular insert fracture	0.07%	0.57%[27], 0.63%[28], 1.12%[29], 3.51%[30]
Intraoperative acetabular insert chip	0.47%	1.8% at 3 to 5 years[31]
Femoral component loosening	0.30%	0.6%[32] at 15 years, 3.0%[33]
Acetabular component loosening	2.53%	10.0%[34]
Acetabular migration	0.10%	Not available
Femoral Subsidence	0.24%	1.23%[35]
Dislocation	3.30%	6.1%[36], 2.23% (range 0.7-7.0%)[37]
Heterotopic bone formation	2.90%	46.0%[38], 13.0% (range 3.0-50.0%)[39]
Revision/femoral stem	0.94%	0.46% at 2 years, 7.83% at 15 years[40], 11.3% at 5.75 years[41]
Revision/femoral head	0.98%	Not available
Revision/acetabular shell	4.42%	43% at 6 years[42], 0.46% at 2 years[43]
Revision/acetabular insert	4.38%	Not available
Revision/bone screws	0.07%	Not available
Revision/other	0.03%	Not available
Osteolysis/polyethylene wear	0.13%	17.0%[44], 4.0% at 7-10 years[45]
Other		
Postoperative femoral fracture	1.01%	0.68%[46], 1.0% (range 0.1-2.1%) for all periprosthetic fractures[47, 48]
Postoperative acetabular fracture	0.0%	(see above)
Postoperative trochanteric fracture	0.20%	0.57%[49] (also, see above)
Genitourinary	3.23%	1.05%[50], 0.8-35.0%[51]
Gastrointestinal	2.15%	1.05%[52], 1.2-4.6%[53]
Pulmonary Embolism	0.44%	1.05%[54], 0.6%[55]
Deep Vein Thrombosis	0.82%	1.3% (40.0-70.0% within the first 3 weeks)[56]
Cardiovascular	4.89%	1.05%[57], 0.5%[58]
Death	3.34%	1.4%[59], 0.18-0.95%[60]

*Data from the following Stryker sponsored clinical studies was used as a basis for this table: Omnifit® HA, ABC/Trident®, Meridian®, Citation®, Secur-Fit™, Accolade® TMZF and Trident® X3®. There were 2,966 total cases (hips) in 2,697 subjects after combining results from these seven studies. Percentages for operative and device related events were calculated by dividing the number of cases with one or more reported event by the number of cases (hips) enrolled. Systemic events were calculated by dividing the number of subjects with one or more reported events by the number of subjects enrolled. The protocols for the Omnifit® HA and ABC/Trident® studies originally required that all AEs be reported; however, after these products became commercially available, the protocols were modified and required that only operative related events be reported. For the ABC/Trident®, this change occurred in February 2003 and for the Omnifit® HA, in December 1990. The protocol for the Trident® X3® and Accolade® TMZF studies required that operative site AEs and any event meeting the definition of a serious event be reported. The protocols for Secur-Fit™, Citation® and Meridian® required that all AEs were reported. Percentages for primary THR taken from published literature represent averages or ranges as noted.

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.

Subjects will have incentives to return for follow-up visits through an optional patient retention program. Subjects will earn points for completing each follow-up visit within the windows outlined in the protocol and without protocol deviations. They will then have the opportunity to redeem their points for a gift (See Appendix G, Patient Retention Program). Use of this retention program by centers is optional.

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 representatives or agents of sponsors appointed 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 a year, with additional visits as necessary. The investigator will allocate adequate time for such monitoring activities. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all study-related documents and study-related facilities and has adequate space to conduct the monitoring visit. The monitor will review all source documents and compare them to the data contained in the CRFs, 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 may be submitted to a regulatory agency 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 46 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 should provide a list of EC/IRB members and their affiliates to Stryker, if available.

All patients considered for this study will be provided a consent form describing this study and providing sufficient information for patients to make an informed decision about their participation. See Appendix E for a copy of the Model Informed Patient Consent. This 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 IRB approved consent form, must be obtained before that patient is submitted to any study procedure. This 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

There is no compensation to subjects for participation in this study. However, subject attrition can occur for a variety of reasons, including a subject's loss of health insurance coverage or denied 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

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

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

16 Publication Plan

It is anticipated that publication of the multi-center study results will be compiled and submitted to a peer-reviewed journal at the time the study cohort reaches 5 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 5-year multi-center publication is submitted. All publications of the data shall be submitted to Stryker for review prior to submission for publication. Stryker shall not edit or otherwise influence the publications other than to ensure that confidential information is not disclosed and that the data is accurately represented. Any publications resulting from this study must be submitted to Stryker 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.

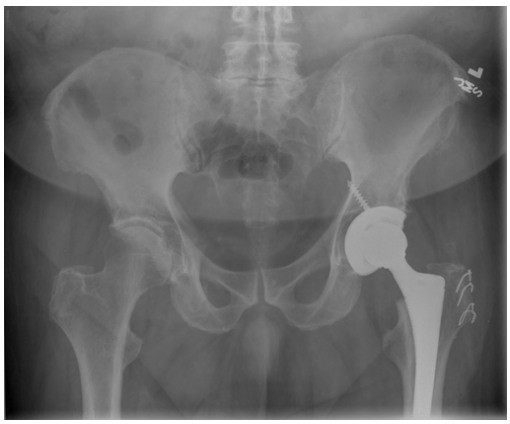

Figure 1. AP Pelvis View – <u>Acceptable</u>

AP Femur

A. Standard technique
   a. The subject should be supine with his/her sacrum flat against the table and legs in full extension, internally rotated 15°.
   b. The film cassette should be placed immediately below the table, parallel to the subject's frontal plane.
   c. The x-ray beam should be directed perpendicular to the film cassette and should be centered toward the center of the involved femoral head.
   d. The distal tip of the femoral stem, femoral head and neck, greater and lesser trochanter and the acetabulum must be visible in this radiograph.

Refer to Figure 2 for an acceptable AP femur radiograph.

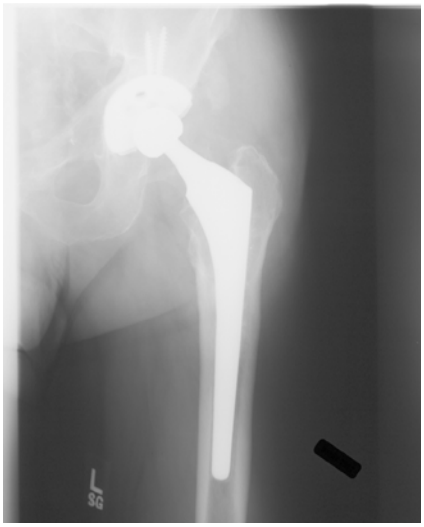

Figure 2. AP Femur View – <u>Acceptable</u>

Refer to Figure 3 for AP subject positioning.

Figure 3. AP 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 and the femur, including the distal tip of the stem, must be visible.

Refer to Figure 3 for an acceptable lateral radiograph.

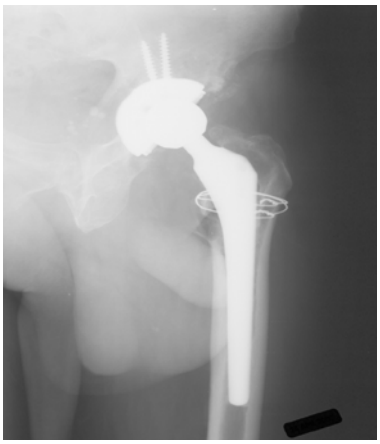

Figure 3. Lateral View – <u>Acceptable</u>

Refer to Figure 4 for subject positioning.

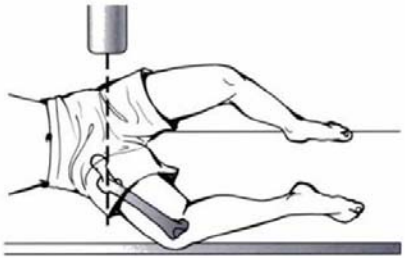

Figure 4. Lateral Positioning

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

[ii] Callaghan, J. J., Rosenberg, A. G., & Rubash, H. E. (Eds.). (1998). *The adult hip*. Lippincott Williams & Wilkins.

[iii] Bono, J. V., McCarthy, J. C., Thornhill, T. S., Bierbaum, B. E., & Turner, R. H. (Eds.). (1999). *Revision total hip arthroplasty*. New York: Spring-Verlag.

Appendix B

Biomechanical Measurement Protocol

The CRFs in Appendix F should be referenced
for all preoperative and postoperative data required.

The following lists biomechanical measurements required preoperatively and postoperatively according to this study protocol. These measurements may not be standard as part of site data collection. This appendix should be referenced in detail so that all source documentation is reflective of non-standard data points collected. ***A complete summary of all preoperative and postoperative data*** *needed can be found in Appendix F.*

BIOMECHANICAL MEASUREMENTS

An independent radiographic reviewer will be identified to assess radiographic stability during the study. For collection of biomechanical measurements, however, the investigator at each site will obtain natural preoperative and replaced postoperative values, as well as create a preoperative plan from templating.

Measurement Guidelines

Measurement of **leg length discrepancy** should be determined from the AP pelvis radiograph by drawing lines across both pelvic teardrops to meet both femurs (Reference Line B in Figure 1, below). These lines are to be used as the main reference lines for measuring the distance to the top of each lesser trochanter (Reference Line C in Figure 1, below).[i] The difference between these distances is the value of leg length discrepancy. From this value, the amount of leg length to be restored may be planned.

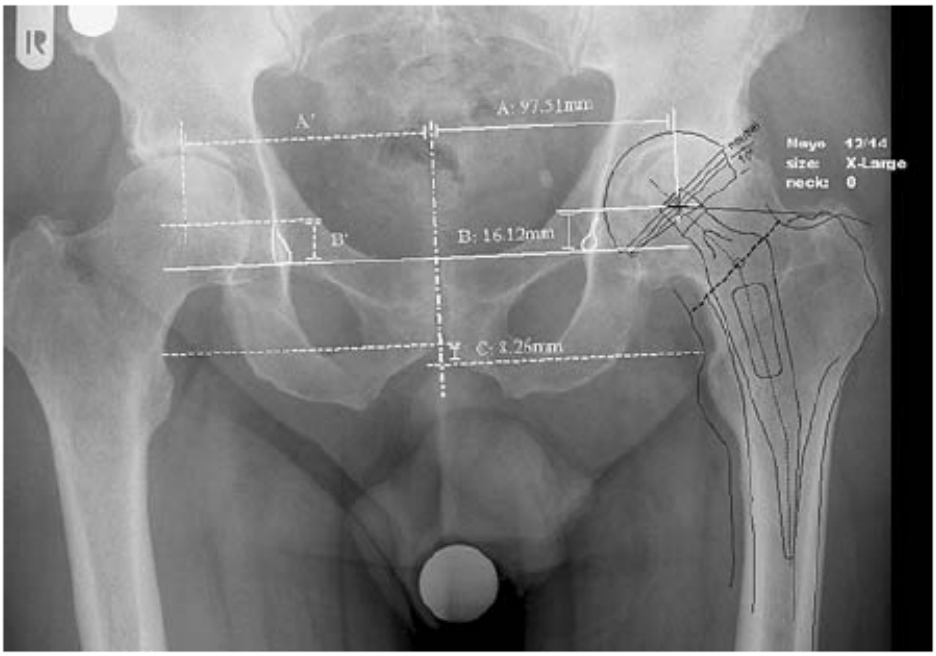


Figure 1.[ii] Reference Lines for Measuring Leg Length Discrepancy

Femoral offset should be determined by measuring the perpendicular distance from the center of the femoral head to the axis along the length of the femur.[iii]

Femoral neck angle is the angle between the long axes of the femoral neck and femoral shaft.[iv]

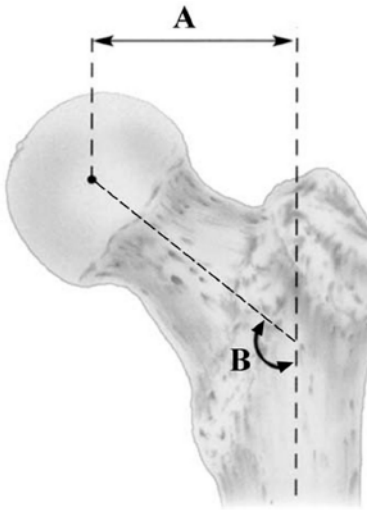


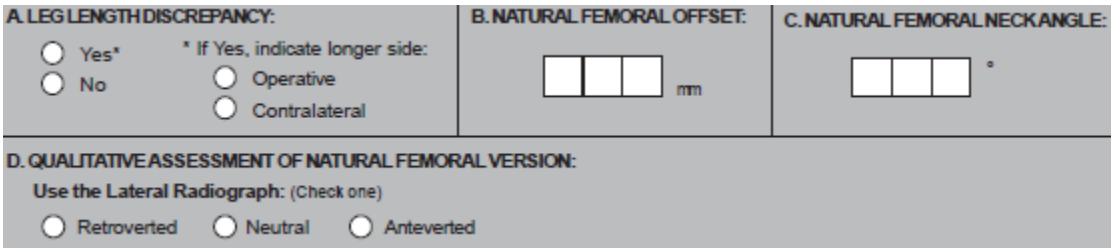
Figure 2.[v] Femoral Offset "A" and Femoral Neck Angle "B"

Qualitative determination of version: Proximal femoral version reflects the relationship of the axis of the femoral neck to the transcondylar axis of the distal femur.[vi] Qualitative determination of whether natural femoral version is retroverted, anteverted or in a state of neutral version should be made from the lateral radiograph.

Natural Preoperative Measurements

Preoperatively, study radiographs will be taken by each investigator. From these preoperative radiographs, the investigator at each site will provide a detailed picture of each patient's level of deformity, as follows.

- **Leg length discrepancy** (centimeters)
- **Natural femoral offset** (millimeters)
- **Natural femoral neck angle** (degrees)
- **Qualitative assessment of natural femoral version** (Retroverted, Neutral, Anteverted)

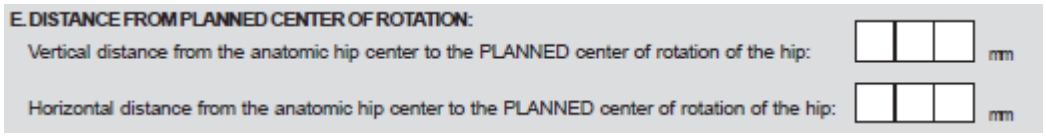


Preoperative Plan

The investigator at each center will create a preoperative biomechanical measurement plan for each case from templating, reflecting desired postoperative measurements and the component sizes, angles and offsets that will be used to achieve these measurements. All component sizes should be corrected for magnification (if any) prior to data collection on the study CRF. This may be accomplished by utilizing an external radiographic marker of known dimension prior to taking the preoperative radiograph.[vii]

Preoperative Distance from Planned Center of Rotation

- **Vertical distance from the anatomic hip center to the planned center of rotation of the hip** (millimeters)
- **Horizontal distance from the anatomic hip center to the planned center of rotation of the hip** (millimeters)



Components to be Used

- **Acetabular cup size**
- **Femoral neck angle** [127°, 132°, 130° (The 130° neck angle is only available in 16° of version.)]
- **Femoral neck length** (millimeters)
- **Femoral head size**
- **Femoral head offset**
- **Femoral stem size***
- **Femoral version** (0°, ±8°, ±16°)

J. ACETABULAR CUP SIZE: ☐☐ mm

K. FEMORAL HEAD OFFSET (mm): (Check one)

◯ -5 ◯ -4 ◯ -2.7 ◯ -2.5 ◯ +0 ◯ +2.5 ◯ +3 ◯ +4 ◯ +5 ◯ +7.5 ◯ +8 ◯ +10 ◯ +12

L. FEMORAL HEAD SIZE: ☐☐ mm

M. FEMORAL NECK ANGLE: (Check one) ◯ 127° ◯ 130° ◯ 132°

N. FEMORAL NECK LENGTH (mm): (Check one) ◯ 30 ◯ 34 ◯ 38 ◯ 42

O. FEMORAL STEM SIZE (mm): (Check one) ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12

P. FEMORAL VERSION: (Check one) ◯ -16° ◯ -8° ◯ 0° ◯ +8° ◯ +16°

*The Rejuvenate® Modular Stem will be available in sizes 7, 8, 9, 10, 11 and 12. The Rejuvenate® Monolithic Stem will be available in sizes 4, 5 and 6; however, **the Rejuvenate® Monolithic Stem may not be used according to this protocol**. Patients requiring a femoral stem in size 4, 5 or 6 should not be enrolled into the study. Investigators should template the femoral stem size to be used prior to completing the Inclusion/Exclusion CRF for enrollment into the study.

Additional Planned Measurements

- **Amount of leg length to restore** (centimeters)
- **Femoral offset to achieve** (millimeters)
- **Qualitative assessment of planned postoperative femoral version** (Retroverted, Neutral, Anteverted)

F. LEG LENGTH TO RESTORE: ☐.☐ cm | G. FEMORAL OFFSET TO ACHIEVE: ☐☐☐ mm

H. PLANNED POSTOPERATIVE FEMORAL VERSION: (Check one) ◯ Retroverted ◯ Neutral ◯ Anteverted

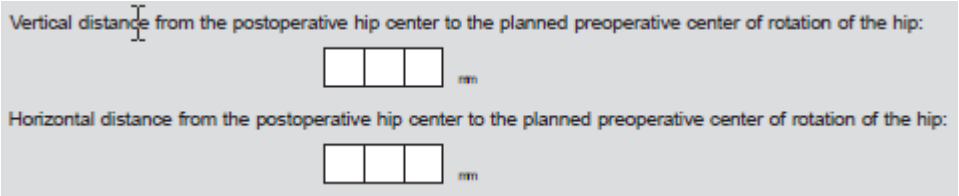
Postoperative Measurements

A postoperative check of biomechanical measurements will be performed by the investigator at each site from the 6-week radiographs to confirm the degree to which the preoperative plan was achieved.

If an AE for instability exists, Stryker will work with an independent radiographic reviewer to re-evaluate the case and confirm whether or not the postoperative biomechanical measurements have changed as a result of the AE. If changes have occurred, the reviewer will continue to assess radiographs at each applicable postoperative interval until the hip has stabilized.

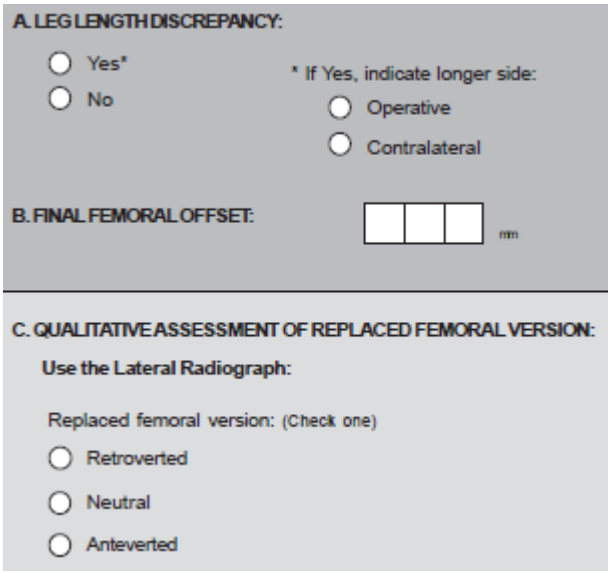
Postoperative Distance from Planned Center of Rotation

- **Vertical distance from the postoperative hip center to the planned preoperative center of rotation of the hip** (millimeters)
- **Horizontal distance from the postoperative hip center to the planned preoperative center of rotation of the hip** (millimeters)



Additional Postoperative Measurements

- **Leg length discrepancy** (centimeters)
- **Final femoral offset** (millimeters)
- **Final femoral neck angle used** [127°, 132°, 130° (The 130° neck angle is only available in 16° of version.)]
- **Qualitative assessment of replaced femoral version** (Retroverted, Neutral, Anteverted)



These postoperative values will be compared to the preoperative plan to evaluate the degree of patient matching achieved with the Rejuvenate® Modular Hip System.

Component sizes used intraoperatively will be automatically determined from catalog numbers provided on the Surgical Details CRF.

[i] Wedemeyer, C., Quitmann, H., Xu, J., Heep, H., von Knoch, M., & Saxler, G. (2007). Digital templating in total hip arthroplasty with the Mayo stem. *Archives of Orthopaedic and Trauma Surgery*.

[ii] Ibid.

[iii] Charles, M.N., Bourne, R.B., Davey, J.R., Greenwald, A.S., Morrey, B.F., & Rorabeck, C.H. (2004). Soft-tissue balancing of the hip: The role of femoral offset restoration. *The Journal of Bone and Joint Surgery, 86,* 1078-1088.

[iv] Ibid.

[v] Ibid.

[vi] Kudrna, J. (2005). Femoral version: Definition, diagnosis, and intraoperative correction with modular femoral components. Retrieved September 23, 2008, from http://www.orthosupersite.com/view.asp?rID=3936

[vii] Bono, J.V. (2004). Digital templating in total hip arthroplasty. *The Journal of Bone and Joint Surgery, 86,* 118-122.

Appendix C

Component List

Rejuvenate® Modular Hip System
Protocol-Specified Component List

FEMORAL NECK COMPONENTS

Neck Description	Catalog Number	Neck Length	Retroversion/ Anteversion
REJUVENATE® MOD NECK 0 V 127/132 BLK 30 MM	NLS-300000B	30 mm	0°
REJUVENATE® MOD NECK 8 AV/RV 127/132 YEL 30 MM	NLV-300800Y	30 mm	8°
REJUVENATE® MOD NECK 8 RV/AV 127/132 GR 30 MM	NLV-300800G	30 mm	8°
REJUVENATE® MOD NECK 16 V 130 PURPLE 30 MM	NLS-301600P	30 mm	16°
REJUVENATE® MOD NECK 0 V 127/132 BLK 34 MM	NLS-340000B	34 mm	0°
REJUVENATE® MOD NECK 8 AV/RV 127/132 YEL 34 MM	NLV-340800Y	34 mm	8°
REJUVENATE® MOD NECK 8 RV/AV 127/132 GR 34 MM	NLV-340800G	34 mm	8°
REJUVENATE® MOD NECK 16 V 130 PURPLE 34 MM	NLS-341600P	34 mm	16°
REJUVENATE® MOD NECK 0 V 127/132 BLK 38 MM	NLS-380000B	38 mm	0°
REJUVENATE® MOD NECK 8 AV/RV 127/132 YEL 38 MM	NLV-380800Y	38 mm	8°
REJUVENATE® MOD NECK 8 RV/AV 127/132 GR 38 MM	NLV-380800G	38 mm	8°
REJUVENATE® MOD NECK 16 V 130 PURPLE 38 MM	NLS-381600P	38 mm	16°
REJUVENATE® MOD NECK 0 V 127/132 BLK 42 MM	NLS-420000B	42 mm	0°
REJUVENATE® MOD NECK 8 AV/RV 127/132 YEL 42 MM	NLV-420800Y	42 mm	8°
REJUVENATE® MOD NECK 8 RV/AV 127/132 GR 42 MM	NLV-420800G	42 mm	8°
REJUVENATE® MOD NECK 16 V 130 PURPLE 42 MM	NLS-421600P	42 mm	16°

FEMORAL STEM COMPONENTS

Stem Size	Catalog #	Stem Description
7	SPT-070000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 7
8	SPT-080000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 8
9	SPT-090000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 9
10	SPT-100000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 10
11	SPT-110000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 11
12	SPT-120000S	REJUVENATE® STRGHT PRFIT TMZF® MOD STEM SIZE 12

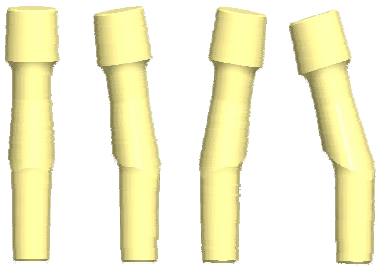
Appendix D

Study Advertisements

Clinical Trial with Rejuvenate® Modular Hip System

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

The **Rejuvenate® Modular Hip System** features a modular hip prosthesis with two components fitting together, allowing the device to be changed based on a patient's anatomy. This allows for more adaptability. With a stem and neck used together, the **Rejuvenate® Modular Hip System** is intended for cementless, press-fit use. It is compatible with other Stryker components as well. This system is currently being sold worldwide and is implanted in patients who need primary hip surgery.



Dr. (name) is one of 10 to 12 surgeons nationwide selected to enroll qualifying patients into this clinical study. The data collected will be used to evaluate both short and long-term (10-year) performance of the components following surgery.

The study includes males and non-pregnant females 18 years of age or older. These patients must be candidates for a primary hip replacement. These patients must also be able to comply with requirements following surgery including weight bearing restrictions and self-evaluation questionnaires. Enrolled patients will be required to come in for an evaluation and x-rays before surgery and follow-up evaluations and x-rays at 6 weeks, 1 year, 2 years, 3 years, 4 years and 5 years. A short follow-up questionnaire will be required annually at years 6 through 10 after surgery. The doctor may choose to perform further follow-up evaluations at 7 years and 10 years.

Meeting all of the above criteria does not guarantee participation in the study. Further consultation and a screening evaluation with the physician are necessary to ensure this is the right study for you. Study personnel at the site will explain

all the details of the study to you so you can make an informed decision as to whether or not you would like to participate.

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

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

Dr. (name)
Practice Name
Telephone Number

Study Coordinator Name
Title
Telephone Number

Appendix E

Model Informed Patient Consent

Model Informed Patient Consent

I. Study Title: Post-market Study of the Stryker Orthopaedics Rejuvenate® Modular Hip System

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 240 subjects from 10 - 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 Rejuvenate® Modular Hip System as compared to the Secur-Fit™ HA monolithic femoral hip stem, through absence of revision of femoral neck and stem (components implanted in your thigh bone) at 5 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 Rejuvenate® Modular Hip System is at least as good as hips implanted with the Secur-Fit™ HA monolithic femoral stem.

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 two 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, 5, 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, 5, 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, 5, 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.

You will have incentives to return for annual follow-up visits through a patient retention program. Patients enrolled into the study are encouraged to complete all of their required follow-up visits. You will earn points for completing each annual follow-up visit within the windows outlined in the protocol and without any protocol deviations. You will then have the opportunity to redeem your points for a gift selected from a specific listing, or save them and work toward a higher-level gift. As the follow-up visits increase in number, the point values associated with the visits will also increase. The monetary value of the gifts is modest and should not influence your decision to participate in the study.

Number of Visits Completed	Award Level	Points
1 visit	A	100 points
2 visits	B	200 points
3 visits	C	300 points
4 visits	D	400 points
5 visits	E	500 points
6 visits	F	600 points
7 visits	G	700 points

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. 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.

VIII. 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.

IX. Device Retrieval Analysis Study

The sponsor of this study is conducting an analysis of retrieved devices in the event that a study component that you have implanted by your physician is removed during the course of the investigation. In the event the device ever requires removal, and with your permission, the sponsor has asked your physician to send your retrieved component to the sponsor for evaluation as part of your participation in the study. Your retrieved study component and your individually identifiable information will not be released to outside parties. The device will not be returned to you, nor will you receive directly the results of any tests, analysis, or evaluations on the returned device.

X. Clinical Trial Website Posting

Information about this study will be posted on the following website: www.clinicaltrials.gov. This website provides general information including, but not limited to, the number of patients enrolled in the study, the primary and secondary objectives/outcomes, and overall demographics (items such as average age, height and weight) of the study group. In no way will specific patient information be posted on this website.

XI. 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.

XII. 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.

XIII. 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>.

XIV. 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

Case Report Forms

Stryker®

325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System
INCLUSION / EXCLUSION

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

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

I. INCLUSION CRITERIA

	Yes	No	
A.	○	○	Patient has signed an IRB approved, study specific Informed Patient Consent Form. DATE INFORMED CONSENT SIGNED: D D / M M M / Y Y Y Y
B.	○	○	Patient is a male or non-pregnant female age 18 years or older at time of study device implantation.
C.	○	○	Patient has primary diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
D.	○	○	Patient is a candidate for a primary cementless total hip replacement.
E.	○	○	Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.
F.	○	○	Patient's operative femur templates to Rejuvenate™ Modular Stem size 7-12.

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

II. EXCLUSION CRITERIA

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

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

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

III. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

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Monitored _____

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Rejuvenate® Modular Hip System

DEMOGRAPHICS

SUBJECT ID: 6 8 (Study #) | ___ (Site #) | ____ (Subject #)

GENERAL INFORMATION

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

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

VISIT DATE: DD / MMM / YYYY

I. DEMOGRAPHICS

A. DATE OF BIRTH: DD / MMM / YYYY

B. HEIGHT: ___ inches

C. WEIGHT: ___ lbs.

D. EDUCATION LEVEL: (Check One)

◯ < High School ◯ High School Diploma ◯ > High School

E. EMPLOYMENT STATUS: (Check One)

◯ Working ◯ Not Working

F. GENDER: (Check One)

◯ Male ◯ Female

G. ETHNICITY: (Check One)

◯ Hispanic or Latino origin

◯ Not Hispanic or Latino origin

H. RACE: (Check all that apply)

☐ American Indian or Alaskan native

☐ Asian

☐ Black or African heritage

☐ Native Hawaiian or other Pacific Islander

☐ White

II. CIGARETTE AND ALCOHOL USE

I. CIGARETTE USE: (Check One)

◯ Non-smoker

◯ Current cigarette smoker

PACKS/DAY: __.__ # YEARS: ___.__

◯ Ex-cigarette smoker

PACKS/DAY: __.__ # YEARS: ___.__

Date Stopped DD / MMM / YYYY

J. ALCOHOL USE: (Check One)

◯ Have never had alcohol

◯ Have not had alcohol in the last year

◯ < 3 drinks a week

◯ 3 - 7 drinks a week

◯ 8 - 14 drinks a week

◯ 15+ drinks a week

III. DIAGNOSIS

K. INITIAL DIAGNOSIS: (Check One)

◯ Osteoarthritis ◯ Traumatic Arthritis ◯ Avascular Necrosis

◯ Other (Specify) _____

SUBJECT ID: 6 8 | Site # | Subject #

GENERAL INFORMATION

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

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

IV. PRESENT MEDICAL STATUS

L. CONCURRENT MEDICAL CONDITION: (Specify)

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

V. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

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325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System

PRE-OP FUNCTIONAL EVALUATION

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

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

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

I. PAIN

A. PAIN (Check One)

- ○ 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 (Check One)

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

C. SUPPORT (Check One)

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

D. DISTANCE WALKED (Check One)

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

III. FUNCTIONAL ACTIVITIES

E. STAIRS (Check One)

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

F. SOCKS / SHOES (Check One)

- ○ With ease
- ○ With difficulty
- ○ Unable

G. SITTING (Check One)

- ○ 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)

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

(Specify) ____ . ____ cm

J. RANGE OF MOTION (Operative side only)

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

K. THIGH PAIN (Operative side only)

Present at current visit: ○ Yes* ○ No

*If Yes, complete the following:

Describe History or Causative Event: ____

Is the Thigh Pain Distal? ○ Yes ○ No

Is the Thigh Pain Activity Limiting? ○ Yes ○ No

Is the Thigh Pain Constant? ○ Yes ○ No

What is the subject's perception of the Thigh Pain level on a One to Ten (1-10) scale?: (Check One)

Very slight pain ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 Worst Pain

IV. COMMENTS

____

INVESTIGATOR NAME (PRINT): ____

INVESTIGATOR SIGNATURE: ____

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

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Monitored ____

14Apr2010

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Rejuvenate® Modular Hip System
PRE-OP BIOMECHANICAL MEASUREMENTS

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

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

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

VISIT: D D / M M M / Y Y Y Y

I. NATURAL PREOPERATIVE MEASUREMENTS

A. LEG LENGTH DISCREPANCY:

○ Yes* ○ No

* If Yes, indicate longer side:
○ Operative ○ Contralateral

B. NATURAL FEMORAL OFFSET: mm

C. NATURAL FEMORAL NECK ANGLE: °

D. QUALITATIVE ASSESSMENT OF NATURAL FEMORAL VERSION:

Use the Lateral Radiograph: (Check one)

○ Retroverted ○ Neutral ○ Anteverted

II. PREOPERATIVE PLAN

E. DISTANCE FROM PLANNED CENTER OF ROTATION:

Vertical distance from the anatomic hip center to the PLANNED center of rotation of the hip: mm

Horizontal distance from the anatomic hip center to the PLANNED center of rotation of the hip: mm

F. LEG LENGTH TO RESTORE: . cm

G. FEMORAL OFFSET TO ACHIEVE: mm

H. PLANNED POSTOPERATIVE FEMORAL VERSION: (Check one) ○ Retroverted ○ Neutral ○ Anteverted

III. PLANNED COMPONENTS FOR USE

I. ACETABULAR CUP: (Check one)

○ Restoration ADM ○ Trident Hemispherical ○ Other (specify) _____

○ Trident PSL ○ Tritanium Primary Hemispherical

J. ACETABULAR CUP SIZE: mm

K. FEMORAL HEAD OFFSET (mm): (Check one)

○ -5 ○ -4 ○ -2.7 ○ -2.5 ○ +0 ○ +2.5 ○ +3 ○ +4 ○ +5 ○ +7.5 ○ +8 ○ +10 ○ +12

L. FEMORAL HEAD SIZE : mm

M. FEMORAL NECK ANGLE: (Check one) ○ 127° ○ 130° ○ 132°

N. FEMORAL NECK LENGTH (mm): (Check one) ○ 30 ○ 34 ○ 38 ○ 42

O. FEMORAL STEM SIZE (mm): (Check one) ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12

P. FEMORAL VERSION: (Check one) ○ -16° ○ -8° ○ 0° ○ +8° ○ +16°

IV. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATORSIGNATURE:

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

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Rejuvenate® Modular Hip System
SURGICAL DETAILS

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

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

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

I. SURGICAL DETAILS

A. APPROACH: (Check one)

- ◯ Anterolateral
- ◯ Dual Incision
- ◯ Lateral
- ◯ Posterolateral / Posterior
- ◯ Other ____

B. MUSCLE REPAIR OR REATTACHMENT REQUIRED?

◯ Yes* ◯ No *If Yes, which muscle group(s)?

- ☐ External Rotators
- ☐ Gluteus Medius
- ☐ Other ____

C. INCISION LENGTH: ___.__ cm

D. DURATION OF SURGERY: Skin to Skin ___ minutes

E. ESTIMATED BLOOD LOSS: ____ cc

F. NAVIGATION USED? ◯ Yes* ◯ No

*If Yes, complete the following:

Plane: ◯ Anatomic ◯ Functional

System Used / Manufacturer: ____ Software Version: ____

Acetabulum:

Reamer Position: Inclination __ ° Version __ °

Specify: ◯ Retroverted ◯ Anteverted ◯ N/A

Final Cup Position: Inclination __ ° Version __ ° or ◯ N/A

Specify: ◯ Retroverted ◯ Anteverted ◯ N/A

Femur: Broach Alignment

Broach Version: __ °

Specify: ◯ Retroverted ◯ Anteverted ◯ N/A

Neck Angle: ___ °

Head Offset: ___.__ mm

Neck Length: __ mm

Planned Change in Leg Length: ___ mm

Planned Change in Offset: ___ mm

Femur: Stem Alignment

Alignment: __ °

◯ Varus ◯ Valgus

Neck Version: __ °

Specify: ◯ Retroverted ◯ Anteverted ◯ N/A

Head Offset: ___.__ mm

Neck Length: __ mm

Combined Version: ___ °

(head, neck angle and acetabulum)

Neck Angle: ___ °

Final Change in Leg Length: ___ mm

Final Change in Offset: ___ mm

Stryker®

325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System
SURGICAL DETAILS

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

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

II. PROSTHESES

G. PROSTHESES - Attach a copy of the label(s)

- **Acetabular Shell**
- **Acetabular Insert**
- **Femoral Bearing Head**
- **Modular Neck**
- **Modular Stem**

H. OTHER? ◯ Yes* ◯ No

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

Other: (Specify) _____
Reference # _____ Lot # _____

Other: (Specify) _____
Reference # _____ Lot # _____

Other: (Specify) _____
Reference # _____ Lot # _____

I. MODULAR NECK VERSION:

◯ Anteverted ◯ Neutral ◯ Retroverted

J. FEMORAL NECK ANGLE USED: (Check one)

◯ 127° ◯ 130° ◯ 132°

K. INTRAOPERATIVE COMPLICATION?

◯ Yes* ◯ No *If Yes, complete AE form.

L. DISCHARGED TO: (Check One)

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

Discharge Date: D D / M M M / Y Y Y Y

III. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

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Entry _____
Verification _____
Monitored _____

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325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System
SF-12v2™

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

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

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

VISIT: ○ Pre-Op ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. SF-12v2™ Health Survey Standard Version

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

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

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

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 (Check one)	○	○	○
b. Climbing several flights of stairs (Check one)	○	○	○

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?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like (Check one)	○	○	○	○	○
b. Were limited in the kind of work or other activities (Check one)	○	○	○	○	○

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)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like (Check one)	○	○	○	○	○
b. Did work or activities less carefully than usual (Check one)	○	○	○	○	○

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325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System
SF-12v2™

SUBJECT ID: 6 8 | | | Study # | Site # | Subject #

GENERAL INFORMATION

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

VISIT: ○ Pre-Op ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. SF-12 (continued)

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

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 <u>during the past 4 weeks.</u> 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 <u>past 4 weeks</u>...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful? (Check one)	○	○	○	○	○
b. Did you have a lot of energy? (Check one)	○	○	○	○	○
c. Have you felt downhearted and depressed? (Check one)	○	○	○	○	○

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

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

Subject, please initial and date here:

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

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14Apr2010

(SF-12v2 Standard, US Version 2.0)

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325 Corporate Drive, Mahwah, NJ 07430

Rejuvenate® Modular Hip System
LOWER EXTREMITY ACTIVITY SCALE (LEAS)

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

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

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

VISIT: ○ Pre-Op ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. LOWER EXTREMITY ACTIVITY SCALE

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

1. ○ I am confined to bed all day.

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

3. ○ I am either in bed or sitting in a chair most of the day.

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

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

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

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

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

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

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**

Subject, please initial and date here:

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

Stamp Date Received:

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Entry _____
Verification _____
Monitored _____

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Rejuvenate® Modular Hip System
POST-OP FUNCTIONAL EVALUATION

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

GENERAL INFORMATION

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

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

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

VISIT: ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

I. PAIN

A. PAIN (Check One)

- ○ 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 (Check One)

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

C. SUPPORT (Check One)

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

D. DISTANCE WALKED (Check One)

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

III. FUNCTIONAL ACTIVITIES

E. STAIRS (Check One)

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

F. SOCKS / SHOES (Check One)

- ○ With ease
- ○ With difficulty
- ○ Unable

G. SITTING (Check One)

- ○ 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)

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

(Specify) ☐.☐ cm

K. RANGE OF MOTION (Operative side only)

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

J. THIGH PAIN (Operative side only)

Present at current visit: ○ Yes* ○ No

*If Yes, complete the following:

Describe History or Causative Event: _____

Is the Thigh Pain Distal? ○ Yes ○ No

Is the Thigh Pain Activity Limiting? ○ Yes ○ No

Is the Thigh Pain Constant? ○ Yes ○ No

What is the subject's perception of the Thigh Pain level on a One to Ten (1-10) scale?: (Check One)

Very slight pain ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 Worst Pain

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Rejuvenate® Modular Hip System
POST-OP FUNCTIONAL EVALUATION

SUBJECT ID: 6 8 (Study #) | ___ (Site #) | ____ (Subject #)

GENERAL INFORMATION

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

VISIT: ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

IV. EVENTS

L. 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.

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

*If Yes, specify: _____

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

*If Yes, specify and check all that apply:

☐ Contralateral Hip ☐ Contralateral Knee ☐ Ipsilateral Knee ☐ Contralateral Shoulder
☐ Ipsilateral Shoulder ☐ Cataract ☐ Other (Specify) _____

*Provide details: _____

O. Is anything currently affecting the subject's function? ○ Yes* ○ No

*If Yes, specify: _____

V. COMMENTS

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

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Rejuvenate® Modular Hip System

POST-OP BIOMECHANICAL MEASUREMENTS

SUBJECT ID: 6 8 (Study #) | ____ (Site #) | ____ (Subject #)

GENERAL INFORMATION

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

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

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

VISIT: ○ 6 Week ○ Unscheduled-Reviewer Collected

I. ACTUAL POSTOPERATIVE MEASUREMENTS

A. LEG LENGTH DISCREPANCY:

○ Yes*
○ No

* If Yes, indicate longer side:
- ○ Operative
- ○ Contralateral

B. FINAL FEMORAL OFFSET:

___ mm

C. QUALITATIVE ASSESSMENT OF REPLACED FEMORAL VERSION:

Use the Lateral Radiograph:

Replaced femoral version: (Check one)

○ Retroverted
○ Neutral
○ Anteverted

D. POSTOPERATIVE DISTANCE FROM PLANNED CENTER OF ROTATION:

Vertical distance from the postoperative hip center to the planned preoperative center of rotation of the hip:

___ mm

Horizontal distance from the postoperative hip center to the planned preoperative center of rotation of the hip:

___ mm

II. COMMENTS

_____

_____

INVESTIGATOR / REVIEWER NAME (PRINT):

INVESTIGATOR / REVIEWER SIGNATURE:

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

Stamp Date Received:

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Receipt _____
Entry _____
Verification _____
Monitored _____

Keep this reminder sheet in the subject's study binder.
Please do not send to Stryker.

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REJUVENATE® MODULAR HIP SYSTEM
X-RAY REMINDER SHEET

Instructions for Stryker Orthopaedics Clinical Study X-ray Labels

1. Based on the protocol's radiographic evaluation schedule, obtain copies of the subject's X-rays.
   a. If the subject is bilateral and the view includes both sides, **two** copies of the films are needed.
   b. For viewing purposes, the film should always be the mirror image (not inverted).
      i. If the subject's operative side is (R), the joint should be on the (L) side of the film when being viewed.
   c. **Markers** for (R) and (L) should be on the correct side.
      i. If incorrect or missing, the film should be marked correctly.

2. **Complete a white X-ray label** to ensure accurate identification of each film. (similar to CRF header information)
   a. Subject ID
   b. Subject Initials
   c. Date of X-ray
   d. Visit Interval
   e. Operative Side
   f. View

3. **For films**, affix the label to the bottom of the film:
   a. Should not obscure the view
   b. Should not obscure the implant
   c. Should not cover the subject imprint details
   d. Should be positioned horizontally according to the view

4. **For digital X-rays**, attach completed unpeeled labels to the CD case and write the Subject ID on the CD.

5. Send the labeled X-rays to **Data Entry** for processing. (Data Entry affixes a color-coded visit interval label over the subject imprint to obscure the subject's personal health information.)

6. When the X-ray label supply is low, please contact the Clinical Study Manager to request more labels.

SUBJECT ID: 6 8 (Study #) | (Site #) | (Subject #)

VISIT: ○ Pre-op ○ 6 Week ○ 1 Year ○ 2 Year ○ 3 Year ○ 4 Year ○ 5 Year ○ 7 Year ○ 10 Year

	Obtained	Not Obtained (Complete and submit one Protocol Deviation Form per interval)	N/A
1. A/P Pelvis	○	○	○
2. A/P Femur	○	○	○
3. Lateral	○	○	○

COMMENTS

Date X-rays Sent: _____ **Tracking Number:** _____

14Apr2010

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Rejuvenate® Modular Hip System
FOLLOW-UP QUESTIONNAIRE

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

QUESTIONNAIRE COMPLETED BY: ○ Visit ○ Mail ○ Phone

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

VISIT : ○ 6 Year ○ 7 Year ○ 8 Year ○ 9 Year ○ 10 Year

I. HIP QUESTIONS

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

Subject comment: _____

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

Subject comment: _____

3. **Have you had any surgery on your study hip during the time since your last study required visit/contact?** ○ **YES*** ○ **NO**

Subject comment: _____

Subject, please initial and date here: _____ **DATE:** D D / M M M / Y Y Y Y

II. FOR COORDINATOR'S USE ONLY

Please specify below for responses marked with an asterisk.

A. *Coordinator, if Yes in Question 1 above, specify, complete Adverse Event form and provide date:

_____
_____
_____

AE Onset Date: D D / M M M / Y Y Y Y

B. *Coordinator, if No in Question 2 above, specify:

_____
_____
_____

C. *Coordinator, if Yes in Question 3 above, specify, complete Adverse Event form and provide date:

_____
_____
_____

AE Onset Date: D D / M M M / Y Y Y Y

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

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Rejuvenate® Modular Hip System
ADVERSE EVENT

SUBJECT ID: 6 8 (Study #) | ____ (Site #) | ____ (Subject #)

GENERAL INFORMATION

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

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

ONSET DATE: __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

I. DESCRIPTION

(Check one event in Section A or Section B)

A. OPERATIVE SITE EVENTS

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

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)

Specify: _____

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

◯ 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? (Check one)

◯ Yes* ◯ No ◯ Uncertain*

*** If Yes or Uncertain, please explain and fax all pages to Stryker within 24 hours.**

_____

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:

__ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

If Serious -- FAX all pages to Stryker within 24 hours.
Fax number: (201) 831-6454. Please include copies of applicable source documentation.

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Rejuvenate® Modular Hip System
ADVERSE EVENT

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

ONSET DATE: __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

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

- ☐ Acetabular Shell __ __ / __ __ __ / __ __ __ __
- ☐ Acetabular Insert __ __ / __ __ __ / __ __ __ __
- ☐ Femoral Bearing Head __ __ / __ __ __ / __ __ __ __
- ☐ Modular Neck / Modular Stem (Complete Study Termination form) __ __ / __ __ __ / __ __ __ __
- ☐ Other _____ __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

RE-OPERATIONS: (Specify)

- ☐ _____ __ __ / __ __ __ / __ __ __ __
- ☐ _____ __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

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

- ☐ _____ __ __ / __ __ __ / __ __ __ __
- ☐ _____ __ __ / __ __ __ / __ __ __ __
- ☐ _____ __ __ / __ __ __ / __ __ __ __
- ☐ _____ __ __ / __ __ __ / __ __ __ __
- ☐ _____ __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

RESOLUTION OF EVENT:

- ◯ Unresolved as of __ __ / __ __ __ / __ __ __ __
- ◯ Resolved as of __ __ / __ __ __ / __ __ __ __ * (D D / M M M / Y Y Y Y)

* Submit copy of this form when event resolved.

IV. COMMENTS

_____

INVESTIGATOR NAME (PRINT): _____

INVESTIGATOR SIGNATURE: _____

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

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Rejuvenate® Modular Hip System

NOTICE OF PROTOCOL DEVIATION

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

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

DATE OF DEVIATION: __ __ / __ __ __ / __ __ __ __ (D D / M M M / Y Y Y Y)

I. DEVIATION INFORMATION

(Report One Deviation per form)

A. TYPE OF DEVIATION (Check one)

○ **Informed Consent:** (Check one)
- ○ Study procedures performed prior to informed consent
- ○ Incorrect informed consent version used
- ○ Other (Specify) _____

○ **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 Stem* ☐ Other (Specify) _____

*(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

(Specify one selection)
- ○ Missed entire visit
- ○ 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
  - ☐ X-ray Unevaluable (i.e. unreadable/poor quality)

(If Deviation in visit, specify each form/X-ray)
- ☐ Biomechanical Measurement
- ☐ Follow-up Questionnaire
- ☐ Functional Evaluation
- ☐ SF-12
- ☐ LEAS
- ☐ X-ray - A/P Pelvis
- ☐ X-ray - A/P Femur
- ☐ X-ray - Lateral

○ **Other:** (Specify) _____

B. Briefly describe the deviation and why this occurred. _____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

For Stryker Use Only

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

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Rejuvenate® Modular Hip System

STUDY TERMINATION

SUBJECT ID: 6 8 (Study #) ____ (Site #) ____ (Subject #)

GENERAL INFORMATION

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

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

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

I. STUDY TERMINATION

A. DID SUBJECT COMPLETE STUDY ACCORDING TO PROTOCOL?

◯ Yes ◯ No* * If No, answer questions B and C

B. CHECK ONE PRIMARY REASON BELOW:

◯ Death (Complete AE form)

◯ Investigative Site Terminated

◯ Lost To Follow-Up

List efforts to contact subject:

1st phone call: __ __ / __ __ __ / __ __ __ __

2nd phone call: __ __ / __ __ __ / __ __ __ __

3rd phone call: __ __ / __ __ __ / __ __ __ __

Certified letter sent: __ __ / __ __ __ / __ __ __ __

Additional efforts: _____

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

◯ Study Device Not Implanted (Specify, complete Protocol Deviation form)

_____

◯ Subject Withdrawal

◯ Surgery Not Performed (Specify) _____

◯ Other (Specify) _____

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

II. COMMENTS

_____

_____

INVESTIGATOR NAME (PRINT):

INVESTIGATOR SIGNATURE:

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

Stamp Date Received:

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Receipt _____

Entry _____

Verification _____

Monitored _____

Appendix G

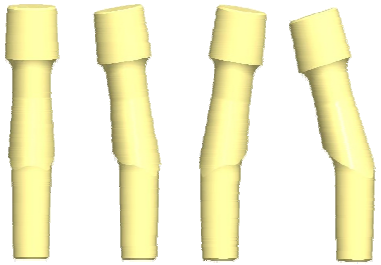
Patient Retention Program

stryker

Orthopaedics

An Open-label Evaluation of the Rejuvenate® Modular Hip System

Patient Retention Program



AWARDS

A Prospective Open-label Evaluation of the Rejuvenate® Modular Hip System

- **Who is eligible to participate?**

  Enrolled subjects for the Rejuvenate® Modular Hip System post-market study who have undergone primary cementless total hip replacement according to the protocol and are returning for the 1-year visit after completion of the 6-week follow-up visit, without deviation

- **How long the program will run?**

  Start of enrollment until 6 months after the last study subject has returned for the 10-year follow-up visit

- **Individual Rewards**

  Subjects advance one prize level for each **annual follow-up visit** completed within the windows outlined in the protocol (visit schedule noted below) and **without any postoperative protocol deviations**. Upon exit from the study, subjects have the opportunity to receive a gift selected from a specific listing that corresponds to the prize level earned. Values may be divided to receive multiple awards. As the annual follow-up visits increase in number, the award level will also increase. For example, a subject that attends all annual follow-up visits would receive a G level award, a subject that has missed one annual follow-up visit or deviated in any one postoperative visit would receive a F level award and so on.

Follow-up Visit
6 weeks (± 3 weeks)
1 year (± 2 months)
2 years (± 2 months)
3 years (± 3 months)
4 years (± 4 months)
5 years (± 4 months)
7 years (± 4 months)
10 years (± 4 months)

Number of Visits Complete	Award Level	Award Value
1 visit	A	100 points
2 visits	B	200 points
3 visits	C	300 points
4 visits	D	400 points
5 visits	E	500 points
6 visits	F	600 points
7 visits	G	700 points

- If a subject would then like to redeem his/her points prior to study withdrawal, they may at any time. The subject would continue in the study, but the amount of points redeemed would be deducted from their total points moving forward. For example:
    - A subject decides to redeem their points after completing the 1-year, 2-year and 3-year visits according to protocol. The subject plans to continue in the study for the 7-year and 10-year time points.
    - The subject may redeem 300 points (or any lesser amount of points in 100-point increments) for completing three postoperative visits according to protocol. If a subject chooses to redeem 300 points, he/she could either receive the Level C award booklet or Level A and Level B booklets at once.
    - As the subject continues in the study, the number of points already redeemed is deducted from the number of points that would have been available for redemption at each later visit. For instance, after 10 years if 300 points were already redeemed, the subject would only be eligible for 400 points upon study closure.
    - The maximum number of points that can be redeemed over the course of the study is 700.

- Bilateral subjects do not accumulate double points. Points are accrued per subject, not per hip enrolled.

- When subjects have completed the study by reaching the 10-year follow-up visit, they request an award booklet and order form from their SC. The award booklet will only contain the awards that the patient is eligible to receive according to the total gift level they have earned at that time. The subject selects the award and completes and mails in the order form. Awards may also be redeemed online at www.ecgy.net.

- All awards will be shipped directly to the subject's address (no P.O. boxes) with postage and/or shipping charges prepaid by Stryker. In the event a parcel arrives in a damaged or unsatisfactory condition, the SC is notified so that Stryker may be informed. Rewards should not be returned without specific instructions.

- Please allow 3 to 6 weeks for delivery. If, in the rare instance, the selection cannot be delivered immediately, the subject will be notified by postcard. If the selection becomes unavailable, it may be substituted with another selection from the same award level. Samples of prizes at each award level follow.