Trident II Acetabular Shell Revision Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center evaluation of the clinical outcomes of the Trident II Acetabular Shell in a revision indication

Sponsor:	*Stryker* *Orthopaedics – Joint Replacement* *325 Corporate Drive* *Mahwah, NJ 07430* *201-831-5000*
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Version	Description	Changed By
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List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
AP	Anteroposterior
BMI	Body Mass Index
CFR	Code of Federal Regulations
fCSM	Functional Clinical Study Manager
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EQ-5D	EuroQol Five Dimensions Questionnaire
FDA	Food and Drug Administration
GCP	International Conference of Harmonisation Good Clinical Practice
HA	Hydroxylapatite
HHS	Harris Hip Score
HIPAA	Health Insurance Portability and Accountability Act
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISO	International Organization for Standardization
LEAS	Lower Extremity Activity Scale
LRM	Laser Rapid Manufacturing
PI	Product Inquiry
PSF	Particle Sintered Foam
QOL	Quality of Life
ROM	Range of Motion
SAE	Serious Adverse Event
SC	Study Coordinator
VR-12	Veterans RAND-12
THA	Total Hip Arthroplasty
UADE	Unanticipated Adverse Device Effect

Study Synopsis

Title	A prospective, post-market, multi-center study of the Trident II Acetabular Shell in a revision indication
Short Title	Trident II Revision Outcomes Study
Protocol Number	79
Phase	Post-market
Methodology	This study will be a prospective, non-randomized evaluation of the Trident II Acetabular Shell for revision of the acetabular component of a previously failed total hip arthroplasty (THA) with a cementless application in a consecutive series of patients who meet the eligibility criteria.
Study Duration	• Enrollment period of 60 months • Follow-up of each revision THA case to 10 years • Approximate 15-year total duration
Study Center(s)	10-15 centers
Hypothesis	The success rate, defined as freedom from acetabular revision for aseptic loosening, for hips implanted with the Trident II Acetabular Shell, is no worse than for hips implanted with similar technology as reported in the literature at five years postoperative.
Objectives	Primary: • To demonstrate, through absence of revision for aseptic loosening at five years postoperative, that acetabular revision with the Trident II Acetabular Shell provides clinical results comparable to similar acetabular components for revision indications. Secondary: • To review radiographic stability of hips implanted with the Trident II Acetabular Shell.

Additional Data Collection	• To assess pain, function and health related quality of life (QOL). The following outcomes measures will be collected:
	  ○ Harris Hip Score (HHS)
	  ○ Veterans RAND-12 (VR-12)
	  ○ Lower Extremity Activity Scale (LEAS)
	  ○ EuroQol-5D (EQ-5D)
	• An additional Follow-Up Questionnaire will be administered in postoperative evaluations 6-week through 10-year to assess patient satisfaction and pain, and to capture adverse events when the patient is not present to complete the HHS.

Number of Subjects	A minimum of 347 cases receiving the Trident II Acetabular Shell will be enrolled into the study.
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 18-85 years of age at the time of study device implantation. C. Patient is a candidate for a revision of a failed acetabular component with a cementless acetabular component. D. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations.

Diagnosis and Main Inclusion/Exclusion Criteria*	Exclusions: E. Patient has a Body Mass Index (BMI) > 45. F. Patient is diagnosed with Inflammatory Arthritis. G. Patient has a non-Stryker retained stem. 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 mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care. J. Patient has compromised bone stock which cannot provide adequate support and/or fixation to the prosthesis. K. 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. L. Patient is immunologically suppressed or receiving 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.

*Although this list is comprehensive from a clinical study patient selection perspective, the Investigator should always review the latest Instructions for Use (IFU) and Surgical Protocol prior to choosing subjects and performing surgery as newer versions may become available following study initiation.

Study Device	Required Components:
	• Trident II Tritanium Acetabular Shell:
	  ○ Clusterhole
	  ○ Solidback
	  ○ Multihole
	• Trident II HA Hemispherical Clusterhole Shell
	• Trident II HA PSL Clusterhole Shell
	  • Acetabular components must be used in a cementless application.
	• If screws are used, only 6.5 mm Low Profile Hex Screws are permissible.
	The following ancillary devices are permissible:
	• Compatible Stryker Modular Dual Mobility (MDM) acetabular liner
	• Compatible Stryker X3 polyethylene inserts
	• Compatible Stryker femoral bearing heads
	• Compatible Stryker femoral stems
	• Hex Dome Hole Plug
	• Restoration Acetabular Wedge Augments

Reference Therapy	Literature control, based on cementless acetabular revision.
Statistical Methodology	Primary: The 90% confidence interval of the success rate will be computed at five years postoperative. For the non-inferiority comparison, the lower bound of this 90% confidence interval will be compared with 90% survival rate. For the superiority comparison, the lower bound of this 90% confidence interval will be compared with 95%. Secondary: • Radiographic stability will be summarized in table format.

Evaluation Schedule

Evaluation	Pre-op X-rays (-1 yr) eCRFs (-4 mos)	Intra op	6 week (±2 wks)	3-6 mos (±2wks)	1 year (±2 mos)	2 year (±2 mos)	3 year (±3 mos)	4 year (±4 mos)	5 year (±4 mos)	6 year (±4 mos)	7 year (±4 mos)	8 year (±4 mos)	9 year (±4 mos)	10 year (±4 mos)
Inclusion/ Exclusion	X													
Demographics	X													
Previous Implant Information		X												
Surgical Details		X												
HHS	X		X		X	X			X		X			X
Postoperative Events			X		X	X			X		X			X
VR-12	X		X		X	X	X	X	X		X			X
LEAS	X		X		X	X	X	X	X		X			X
EQ-5D	X		X		X	X	X	X	X		X			X
Radiographs: Low AP Pelvis, Lateral	X		X	X	X	X			X		X			X
Follow-up Questionnaire*			X	X	X	X	X	X	X	X	X	X	X	X

HHS: The HHS is an assessment that measures function, pain, deformity and motion.
VR-12: The VR-12 is a self-administered patient evaluation that evaluates general health and well-being.
Postoperative Events: The Postoperative Events form is a questionnaire completed by the Investigator intended to provide information on the patient's health status since the last follow-up visit.
LEAS: The LEAS is a self-administered patient evaluation designed to reflect patient activity.
EQ-5D: The EQ-5D is a standardized instrument for use as a measure of health outcome.
*Follow-up Questionnaire: The Follow-up Questionnaire is a questionnaire intended to provide information on patient satisfaction, pain, and survivorship. *Only administered when the patient is not present to complete the HHS.
Low AP Pelvis: Standard radiographic view of the pelvis containing bilateral hips and demonstrating the iliac bone, sacrum, pubis, ischium, femoral heads and necks, and greater or lesser trochanters.
Lateral: Standard radiographic view of the hip joint (can be the Lauenstein lateral, frog leg lateral or cross-table lateral) demonstrating complete visualization of the hip joint and femoral neck.

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

Total hip arthroplasty (THA) is one of the most clinically successful and cost-effective interventions in health care.[1] The use of highly porous metals in cementless THA has yielded successful results at mid- to long-term follow-up.[2] However, despite the improvements in implant designs and surgical techniques, there are cases in which the acetabular component is revised due to loosening, wear, or infection. Specifically, as reported in the literature, there is a 2% risk of revision for primary THA in the first 18 months after the index procedure and 1% thereafter in a 12-year study period.[3]

Due to the expanding indications and aging population, the demand for THA is projected to increase by 174% by 2030, therefore triggering a subsequent rise in revision THA.[6,7] During revision THA surgeons are confronted with greater technical and decision-making challenges due to the need to manage acetabular bone loss and poor quality of bone; all the while selecting proper implant and fixation strategy.[4] As a result of these challenges, this can lead to compromised initial stability, which in turn leads to lack of long-term fixation and failure. However, with advances in cementless acetabular revision there have been improved results over the less than optimal cemented fixation.[5]

In cases utilizing cementless acetabular components there is a required initial implant stability to allow for biologic fixation, which provides long-term durability of the prosthesis when properly achieved.[8] To this end, there are several surface options available for cementless acetabular fixation; titanium fibermesh, sintered bead surfaces, plasma spray and trabecular metal are some widely used examples, all with good clinical history.[9,10]

Particularly, the use of porous coated cementless cups in revision THA offers optimal biocompatibility therefore offering biological fixation.[11] Delanois[6] et al. published Kaplan Meier survivorship results on highly-porous titanium cups of patients who underwent revision THA,

reporting 97% survivorship at five years. Similar positive results have been reported at shorter time points for both porous-coated anatomic biologic fixation cups (6.6% loosening after 20 months) and titanium mesh ingrowth cups (1.4% failure after 41-month follow-up).[11] Furthermore, Khatod[13] et al. published revision femoral and acetabular rates of 39.43% (248 of 629 cases), and more specifically re-revision femoral and acetabular rates of 31.74% (20 of 63 cases) at five years.

Tritanium technology was developed to provide a three-dimensional Titanium matrix that resembles cancellous bone, allowing for enhanced acetabular fixation.[2,12]

The Trident II Tritanium Acetabular Shell is a hemispherical acetabular shell indicated for cementless application. The Trident II HA Acetabular Shell is a hemispherical hydroxylapatite coated acetabular shell indicated for cementless application. Both shells are sterile, single-use devices indicated for use in revision total hip arthroplasty. The Trident II Clusterhole HA Acetabular Shells are available in both Hemispherical and Peripheral Self-Locking (PSL) outer geometry configurations and are compatible with all Trident polyethylene inserts, Trident Constrained Acetabular Inserts, and MDM liners. The Trident II Clusterhole HA Acetabular Shells are fabricated from forged Titanium (Ti-6Al-4V) ELI alloy per ASTM F136. The shells feature a coarse surface that provides initial fixation for cementless hip arthroplasty. The outer surface is coated with Commercially Pure (CP) Titanium followed by Hydroxylapatite powder (PureFix HA), which are each applied separately via a plasma spray process. The shell is subsequently machined to achieve the final product dimensions. The Trident II Tritanium Acetabular Shell and its predicate device, the Stryker Tritanium Acetabular Shell, have similar properties, with differences noted in material and manufacturing processes. The Trident II Tritanium Acetabular Shell is manufactured from Ti-6Al-4V via Laser Rapid Manufacturing (LRM) technology, as opposed to the Particle Sintered Foam (PSF) technology used to manufacture the Tritanium PSF Acetabular Shell coating from commercially pure titanium.

2 Clinical Study Plan

2.1 Study Design

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

2.2 Study Centers

2.2.1 Centers for Data Collection

Cases will be enrolled at ten to fifteen centers. To allow for a learning curve with the use of the device, enrollment of cases into the study will commence when three cases have been completed at the center using the Trident II Acetabular Shell. The enrollment goal is a minimum of 25 cases per center utilizing the Trident II Acetabular Shell but will vary dependent upon the number of participating centers. Although a goal is presented, there is no maximum limit to the number of cases that a center may enroll. In the event that a center far exceeds the enrollment goal, Stryker may ask the center to cease enrollment so as not to skew the data. All participating centers will comply with the federal regulations regarding patient informed consent and Institutional Review Board (IRB) approval. Non-compliance of a study center may result in termination of the center's participation in the study.

2.3 Number of Subjects

A minimum of 347 cases receiving the Trident II Tritanium or Trident II HA Acetabular Shell will be enrolled into the study.

3 Device Description

3.1 Study Device

The Trident II Tritanium Acetabular Shell is cleared for use in the United States under K161569 and K171768. The Trident II HA Shells have been cleared under K171768. See **Appendix A** for the FDA clearance letters.

The Trident II Tritanium Acetabular Shell is a hemispherical acetabular shell with a 3D engineered porous surface for biological fixation, made of Ti-6Al-4V alloy through additive manufacturing. The shell is built upon the design features and clinical history of the existing Tritanium Solid, Cluster, Multihole and Trident HA acetabular shells. Although they do have similar properties,

the material and manufacturing processes are different; the Trident II Tritanium hemispherical shell is manufactured from Ti-6Al-4V via Laser Rapid Manufacturing (LRM) technology, as opposed to the Particle Sintered Foam (PSF) technology used to manufacture the Tritanium PSF Acetabular Shell coating from commercially pure titanium. The Trident II HA Acetabular Shell is a hemispherical shell with hydroxylapatite coating and is indicated for cementless application. The Trident II HA Shells are an extension of the overall Trident System product line and feature the same insert locking mechanism as the current Trident product line. This advanced technology is designed to address the need for improved initial and biological fixation. The Trident II Tritanium Acetabular Shell, intended for use in a cementless application, is available in sizes from 42 mm through 72 mm and is compatible with Trident polyethylene liners, Mobile Dual Mobility (MDM) acetabular liners, and Trident II Tritanium acetabular screws. The Trident II HA Acetabular Shell is available in sizes 42 mm through 66 mm. Data in support of these marketing claims will be collected as part of the protocol.

The Trident II Tritanium and Trident II HA Acetabular Shell Product Labeling can be found in **Appendix B**.

The following acetabular component catalog numbers are permissible according to this study protocol and are in the following format, where 'XXY' varies by size:

702-04-XXY, 700-04-XXY, 709-04-XXY, 702-11-XXX, 742-11-XXX

The following bone screw catalog numbers are permissible according to this study protocol and are in the following format, where 'XX' varies by length:

7030-65XX

The full listing of permissible acetabular component and bone screw catalog numbers may be found in **Appendix C**.

3.2 Ancillary Devices

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

- Compatible Stryker acetabular inserts
- Compatible Stryker MDM acetabular liner

- Compatible Stryker femoral bearing heads
- Compatible Stryker femoral stems
- Restoration Acetabular Wedge Augments
- 6.5mm Low Profile Hex Screw
- Hex Dome Hole Plug

The compatible Stryker acetabular inserts, acetabular liner, and heads are listed in the surgical protocol. All compatible ancillary devices will be used on-label only.

For reference, compatible Stryker femoral heads, acetabular liners and inserts are listed in **Tables 2-10** below. In the case of any uncertainty regarding device compatibility, the current versions of the Trident II Acetabular Shell surgical protocols should be reviewed.

Table 1: Trident II Tritanium Shell/Femoral Head/X3 Liner Compatibility

Shell Size, Liner Alpha Code, and Head Size (mm)

Solidback & Clusterhole *		42	44	46	48,50	52,54	56,58	60,62	64,66		
Multihole**		42	44	46	48,50	52,54	56,58	60,62	64,66	68,70	72
Liner Alpha Code		A	B	C	D	E	F	G	H	I	J
Anatomic Femoral Heads	44mm	–	–	–	–	–	3.8	5.4	7.1	8.6	10.6
	40mm	–	–	–	–	3.8	5.8	7.4	9.1	10.6	12.6
	36mm	–	–	–	3.9	5.9	7.9	9.4	11.2	12.7	14.7
Femoral Heads	32mm	–	3.9	4.9	5.9	7.9	9.9	11.4	13.2	14.7	16.7
	28mm	4.9	5.9	6.9	7.9	9.9	11.9	13.4	15.2	16.7	18.7
	26mm	–	–	7.9	8.9	10.9	12.9	14.4	16.2	17.7	19.7
	22mm	7.8	8.8	9.8	10.8	12.8	14.8	16.3	18.1	19.6	21.6

***Clusterhole shell sizes 42mm-50mm have 3-holes, and 52mm-66mm have 5-holes.**

****Multihole shell sizes 42-46mm have 8 holes, 48-50mm have 9 holes, 52-54mm have 11 holes, and 56-72mm have 13 holes.**

Table 2: Trident II Tritanium Shell/Insert Compatibility

Alpha Code	Trident II Tritanium Shell Size (mm)	Trident 0°, 10° Inserts (mm)	Trident Eccentric 0°, 10° Inserts (mm)	Trident Elevated Rim Inserts (mm)
A	42	22, 28**	–	–
B	44	22, 28**, 32**	28*	–
C	46	22, 26, 28, 32**	28	28
D	48, 50	22, 26, 28, 32, 36**	28, 32	28
E	52, 54	22, 26, 28, 32, 36, 40**	28, 32, 36	28, 32, 36
F	56, 58	22, 26, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36
G	60, 62	22, 26, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36
H	64, 66	22, 26, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36
I	68, 70	22, 26, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36
J	72	22, 26, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36

***Available in 0°only.**
**** Available in X3 only and 0° only.**

Table 3: Trident II Tritanium Shell/MDM Liner/Insert Compatibility

Shell Size (mm), Liner Alpha Code

Trident II Tritanium Shell	46	48, 50	52, 54	56, 58	60, 62	64, 66	68,70	72
Liner Alpha Code	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
MDM CoCr Liner	36C	38D	42E	46F	48G	52H	54I	58J
Poly Insert OD (mm)	36	38	42	46	48	52	54	58
Poly Insert ID (mm)	22.2	22.2	28	28	28	28	28	28
Nominal Poly Thickness (mm)	6.7	7.7	6.8	8.8	9.8	11.8	12.8	14.8

Table 4: Trident II PSL Clusterhole HA Femoral head, X3 Liner and Shell Compatibility

Shell size, liner alpha code, poly thickness and head size (mm)

Trident II PSL Clusterhole HA*		**42**	**44**	**46**	**48, 50**	**52, 54**	**56, 58**	**60, 62**	**64, 66**
Alpha code		**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Anatomic femoral heads	44mm	—	—	—	—	—	3.8	5.4	7.1
	40mm	—	—	—	—	3.8	5.8	7.4	9.1
	36mm	—	—	—	3.9	5.9	7.9	9.4	11.2
Femoral heads	32mm	—	3.9	4.9	5.9	7.9	9.9	11.4	13.2
	28mm	4.9	5.9	6.9	7.9	9.9	11.9	13.4	15.2
	22mm	7.8	8.8	9.8	10.8	12.8	14.8	16.3	18.1

***Clusterhole shell sizes 42mm-50mm have 3-holes, and 52mm-66mm have 5-holes.**

Table 5: Trident II PSL Clusterhole HA Shell

Trident II PSL Clusterhole HA Shell

Alpha code	**Trident II PSL Clusterhole HA Shell size (mm)**	**Trident 0°, 10° Inserts (mm)**	**Trident Eccentric 0°, 10° Inserts (mm)**	**Trident Elevated Rim Inserts (mm)**	**Trident 0° Constrained Inserts (mm)**	**Trident 10° Constrained Inserts (mm)**
A	42	22, 28**	—	—	—	—
B	44	22, 28**, 32**	28*	—	—	—
C	46	22, 28, 32**	28	28	—	—
D	48, 50	22, 28, 32, 36**	28, 32	28	22	—
E	52, 54	22, 28, 32, 36, 40**	28, 32, 36	28, 32, 36	22	22
F	56, 58	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	28	22
G	60, 62	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	28	28
H	64, 66	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	32	28

***Available in 0˚only**
****** **Available in X3 only and 0˚ only**

Table 6: Trident II PSL Clusterhole HA Shell MDM Liner and Insert Compatibility

Shell size (mm), liner alpha code

Trident II PSL Clusterhole HA Shell	**46**	**48, 50**	**52, 54**	**56, 58**	**60, 62**	**64, 66**
Alpha code	**C**	**D**	**E**	**F**	**G**	**H**
MDM CoCr Liner	36C	38D	42E	46F	48G	52H
Poly Insert OD (mm)	36	38	42	46	48	52
Poly Insert ID (mm)	22.2	22.2	28	28	28	28
Nominal poly thickness (mm)	6.7	7.7	6.8	8.8	9.8	11.8

Table 7: Trident II Clusterhole HA: Femoral head, X3 Liner and Shell Compatibility

Shell size, liner alpha code, poly thickness and head size (mm)

Trident II Clusterhole HA*		**42**	**44**	**46**	**48, 50**	**52, 54**	**56, 58**	**60, 62**	**64, 66**
Alpha code		**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Anatomic femoral heads	44mm	—	—	—	—	—	3.8	5.4	7.1
	40mm	—	—	—	—	3.8	5.8	7.4	9.1
	36mm	—	—	—	3.9	5.9	7.9	9.4	11.2
Femoral heads	32mm	—	3.9	4.9	5.9	7.9	9.9	11.4	13.2
	28mm	4.9	5.9	6.9	7.9	9.9	11.9	13.4	15.2
	22mm	7.8	8.8	9.8	10.8	12.8	14.8	16.3	18.1

***Clusterhole shell sizes 42mm-50mm have 3-holes, and 52mm-66mm have 5-holes.**

Table 8: Trident II Clusterhole HA Shell

Trident II Clusterhole HA Shell

Alpha code	**Trident II Clusterhole HA Shell size (mm)**	**Trident 0°, 10° Inserts (mm)**	**Trident Eccentric 0°, 10° Inserts (mm)**	**Trident Elevated Rim Inserts (mm)**	**Trident 0° Constrained Inserts (mm)**	**Trident 10° Constrained Inserts (mm)**
A	42	22, 28**	—	—	—	—
B	44	22, 28**, 32**	28*	—	—	—
C	46	22, 28, 32**	28	28	—	—
D	48, 50	22, 28, 32, 36**	28, 32	28	22	—
E	52, 54	22, 28, 32, 36, 40**	28, 32, 36	28, 32, 36	22	22
F	56, 58	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	28	22
G	60, 62	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	28	28
H	64, 66	22, 28, 32, 36, 40**, 44**	28, 32, 36	28, 32, 36	32	28

***Available in 0˚only**
****** Available in X3 only and 0˚ only**

Table 9: Trident II Clusterhole HA: MDM Liner and Insert Compatibility

Shell size (mm), liner alpha code

Trident II Clusterhole HA Shell	**46**	**48, 50**	**52, 54**	**56, 58**	**60, 62**	**64, 66**
Alpha code	**C**	**D**	**E**	**F**	**G**	**H**
MDM CoCr Liner	36C	38D	42E	46F	48G	52H
Poly Insert OD (mm)	36	38	42	46	48	52
Poly Insert ID (mm)	22.2	22.2	28	28	28	28
Nominal poly thickness (mm)	6.7	7.7	6.8	8.8	9.8	11.8

3.3 Device Implantation

All cases included in the analysis will receive the Trident II Acetabular Shell, in a revision setting, using manual instrumentation with an on-label approach. Only cases using an on-label approach in a revision setting may be included in the analysis.

4 Study Procedures

4.1 Subject Recruitment and Screening

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

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 Informed Patient Consent Form prior to participation in the study, as well as prior to any data collection.

4.2 Patient Informed Consent and Guidelines

All patients for this study will be provided an Informed Patient Consent Form describing this study and providing sufficient information for them to make an informed decision about their participation. The Informed Patient Consent Form must contain all elements required by the FDA under 21 CFR Part 50, in addition to any other elements required by state, local and institutional policies. See **Appendix D** for a copy of the applicable Model Informed Patient Consent. This will be submitted with the protocol for review and approval by each institution's overseeing 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 Informed Patient Consent Form, must be obtained before that patient is submitted to any protocol related procedures that are not part of normal care. Written documentation of consent must be provided on the Informed Patient Consent Form's signature page in addition to a note in the patient medical records indicating the date that consent was obtained. The investigator-designated research professional obtaining the consent must also sign this Informed Patient Consent Form. The

patient or his/her legal representative should receive a signed copy of the Informed Patient Consent Form, according to GCP guidelines.

The procedure for obtaining informed consent is outlined below:

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

4.3 Early Withdrawal or Termination of Subjects

When and How to Withdraw Subjects

In the event that a subject is discontinued by the investigative center prior to the final study evaluation, the subject will be notified by the center that he/she is no longer in the study and a Study Termination eCRF will be completed. If the reason for termination involves the study device not being implanted or surgery not performed, the subject will also be censored from analysis.

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

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

Revision or removal of the Trident II Acetabular Shell for any reason constitutes a failure and a study termination for the subject.

If revision of the femoral head, femoral stem, acetabular insert, or acetabular liner is required during the study, the event does not constitute a failure or study termination.

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

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

5 Evaluation Tools

5.1 Objective Outcomes

5.1.1 Radiographs and HHS

To assess radiographic stability, radiographs will be taken and collected in the Low AP Pelvis and Lateral views for the preoperative, 6-week, 3-6 months, 1-year, 2-year, 5-year, 7-year, and 10-year intervals.

The Low AP Pelvis view allows for observation of any conditions involving the sacral wings, iliac bones, ischium, pubis as well as the femoral head and neck. The Lateral view allows for evaluation of the entire hip joint as well as the femoral head, neck and proximal shaft.[14] Suggested radiographic technique for the views required is included in **Appendix E**.

Radiographs will be evaluated by an independent reviewer throughout the course of the study. Radiographic analysis of the acetabular component will employ three zones (Zone 1 – Zone 3) in the AP views. [15], [16] Numerous parameters will be reviewed by zone, including radiolucency and migration, in addition to overall cup/shell stability. Radiolucency in at least 50% of a zone and measuring at least 1 mm in width is defined as radiolucency present. Cases that present with migration of greater than 5 mm in any direction or at least 2 mm radiolucency in all zones will be considered radiographic failures.

Clinical outcomes will be evaluated via the HHS including pain, motion and function, preoperatively and at the 6-week, 1-year, 2-year, 5-year, 7-year and 10-year intervals.

5.2 Patient Reported Outcomes

Patient outcomes data will also be collected via patient questionnaires. During the preoperative, 6-week, 1-year, 2-year, 3-year, 4-year, 5-year, 7-year and 10-year follow-up visits, the VR-12, LEAS and EQ-5D are required. In addition, all subjects will complete a brief satisfaction questionnaire at the 6-week, 3-6 month, and annually through the 10-year follow-up interval when a HHS is not available.

6 Adverse Events

6.1 Reporting of Adverse Events

The AE reporting requirements for this study are as follows:

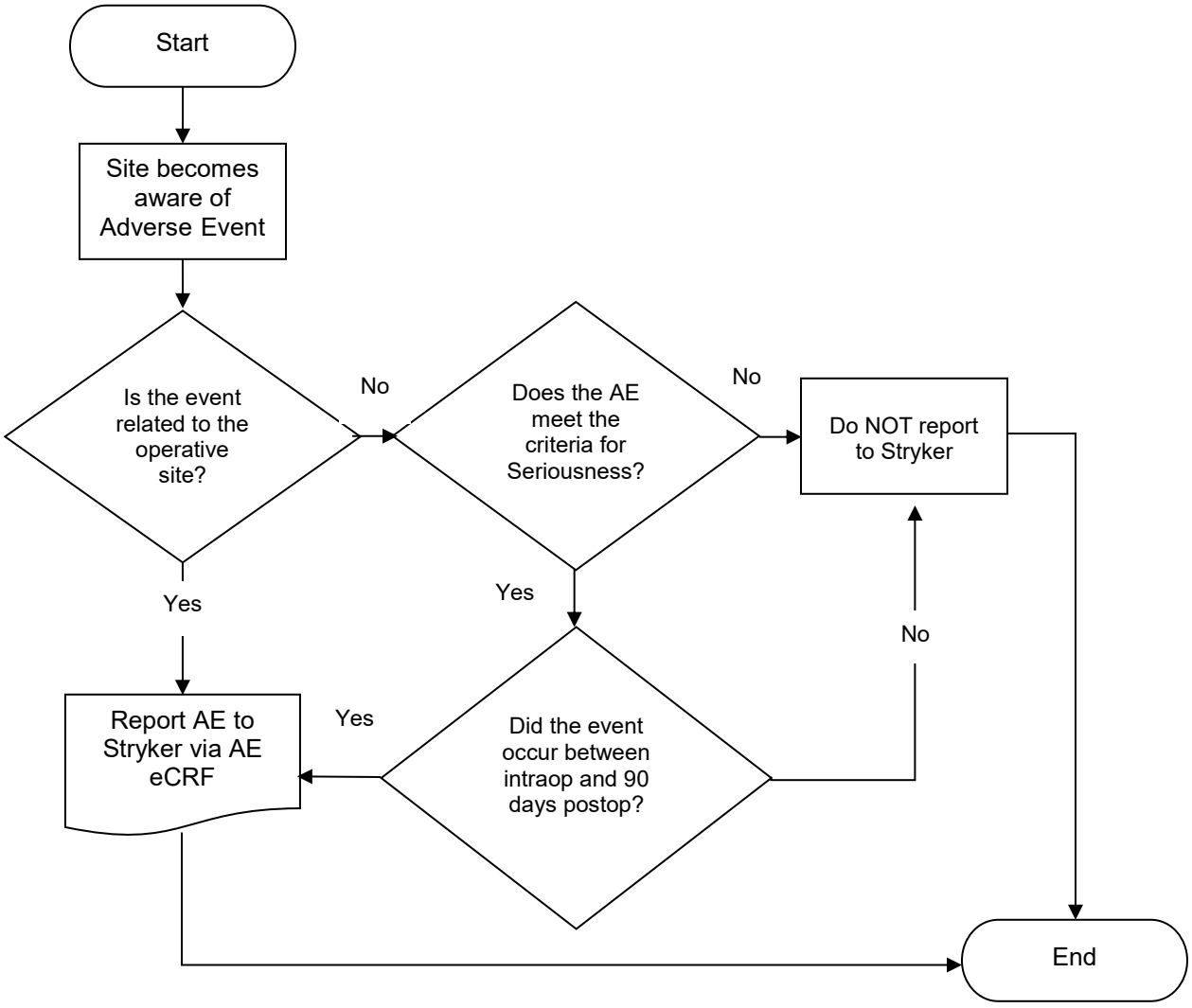
- All AEs that meet the definition of serious and occur from intraoperative to 90 days postoperative
- All AEs related to the operative site, regardless of seriousness or time of occurrence

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

Additionally, SCs will be responsible for following up with the subjects regarding any questionable responses received on the Follow-up Questionnaire collected in lieu of the completion of a HHS at the 6-week through 10-year intervals. If it is determined upon this further investigation that a protocol-defined AE has occurred, the SC will be responsible for completing an AE eCRF, submitting the event to Stryker and reporting to the IRB as required.

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

Figure 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 eCRF. From the time of consent forward, any new clinically significant findings or abnormalities that meet the definition of a protocol defined AE must also be recorded and documented as an AE.

Adverse Event Reporting Period

The study period during which AEs must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. The start of study procedures is considered to be the point of consent. Any AEs that fit the protocol defined reportable events must be reported from the time of consent until study completion.

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

All operative site events occurring at any time as well as all serious adverse events (SAEs) occurring from the intraoperative timepoint to 90 days postoperative will be collected and compared to published data. It is expected that the AE rates reported for the Trident II Acetabular Shell will be comparable to those reported in the literature for other revision cementless acetabular shells on the market.

6.2 General Adverse Event Definitions

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

Adverse Event

An **AE** is any untoward medical occurrence in a clinical investigation subject, which changes the medical baseline of the subject. An AE can be an unfavorable and unintended sign, symptom or

disease, whether or not related to the study device (AEs may also be referred to as complications). See **Section 6.1, Reporting of Adverse Events**, for the AE reporting requirements for this study.

Anticipated Adverse Event

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

Serious Adverse Event

A **SAE** meets one or more of the following definitions:

- Led to death
- Led to serious deterioration in the health of the subject, that either resulted in the following:
    - A life-threatening illness or injury
    - A permanent impairment of a body structure or a body function
    - An in-patient or prolonged hospitalization
    - A medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- Led to foetal distress, foetal death or a congenital abnormality or birth defect

Adverse Device Effect

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

Unanticipated Adverse Device Effect

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

6.3 Study Sponsor Notification by Investigator

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

AEs that require time sensitive reporting:

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

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

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

• Subject number • A description of the event • Date of onset • Current status	• Whether study treatment was discontinued • Investigator assessment of the association between the event and the study treatment

An AE eCRF for an AE meeting the criteria above should be completed within 24 hours of the investigative center's awareness, and the de-identified source documentation should be submitted to Stryker within 24 hours of the investigative center's awareness. These reports will be evaluated by Stryker to determine if a Product Inquiry (PI) is required.

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

6.3.1 Institutional Review Board Notification by Investigator

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

6.3.2 Device Retrieval Process

If the study device is removed for any reason, Stryker may retrieve the Trident II Acetabular Shell and/or adjacent tissues for analysis to help characterize potential device-related complications. In the event that the Trident II Acetabular Shell is removed from a study subject, the procedure outlined in the Retrieved Implant Analysis Protocol **(Appendix F)** should be followed, as allowed by the patient consent, hospital and institution. In addition:

1. When revision of a study subject is scheduled, the SC should contact the Clinical Study Manager (CSM) or other Stryker Clinical Research personnel assigned to the project, as soon as possible.
2. Stryker Clinical Research will send a retrieval container to the SC.
3. After the device is explanted, the SC or an identified Stryker field representative will retrieve the device and place it in the retrieval container, following the instructions in **Appendix F**.
4. The SC, an identified field representative or Stryker Clinical Research will complete a PI.
5. If not completed by Stryker Clinical Research, the PI should be faxed or emailed to Stryker Product Surveillance at 201-831-6775 or soprodexreports@stryker.com, as well as to Stryker Clinical Research at 201-831-6454 or to the Clinical Research email addresses listed on the Sponsor Contact Sheet.
6. The PI should be attached to the retrieval container and sent to Product Surveillance. A de-identified operative report should be included, when available.
7. Stryker Clinical Research will follow up with Product Surveillance to obtain a PI number.
8. A summary of results will be provided to the investigator upon his/her request.

6.4 Recording of Adverse Events

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

6.5 Medical Monitoring

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

7 Data Management

7.1 Database

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

Radiographic images will be collected by each center and uploaded into Stryker's medical imaging platform. This platform allows quick and compliant upload and review of medical images and data where they can be accessed by Stryker. The platform also enables secure sharing of documents with and issues queries to, participating sites. Quality control of the images will be managed by designated Stryker personnel. An independent reviewer will perform review of X-rays and transcribe measurements to Stryker radiographic evaluation forms. Draft specifications to support radiographic evaluation forms are provided in **Appendix H**.

7.2 Confidentiality

This study will comply with the 2002 HIPAA privacy rule. As such, Stryker will only collect that information which is necessary to support the objectives of the study. Stryker has a process to filter out identifying information in the data received during the course of the study. In the case that identifying information is inadvertently received, Stryker will redact and/or return the same in order to ensure no further disclosure. Study subjects will authorize Stryker and its affiliates to receive, retain and 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, as described in the patient consent.

7.3 Source Documents

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

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

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

7.4 Electronic Case Report Forms

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

7.5 Data Queries

If errors or omissions are noted by Stryker upon review of the data entered into the eCRFs, a data query will be sent to the center within the EDC system. Queries should be answered in a clear and comprehensible manner. If the clarification requires a change to study data, the personnel delegated to enter EDC data must update the data directly in the EDC system. The query will be closed upon an acceptable response. The investigative center will be required to reapply their electronic signature to the modified eCRF.

7.6 Protocol Deviations

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

- Informed consent deviations, including but not limited to:
    - Study procedures performed prior to informed consent
    - Incorrect informed consent version used
- Patient enrolled does not meet the inclusion/exclusion criteria
- Protocol specified study component(s) not implanted
- Off label surgical approach
- Off label component usage
    - If the stem is not a Stryker device it must be revised to a compatible Stryker component or the patient will be censored

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

7.7 Records Retention

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

8 Statistical Plan

8.1 Study Objectives

8.1.1 Primary Objective Analysis

The primary hypothesis to be tested will be that the success rate at five years postoperative with the Trident II Acetabular Shell is not worse than 95% with a non-inferiority margin of 5%. That is, the following hypothesis will be tested:

H0: Pt <= 95% - 5% HA: Pt >95 % - 5%

Here, Pt is the success rate at five years postoperative with the Trident II Acetabular Shell. Case success at five years is defined as no incidence of revision and removal of Trident II Acetabular Shell for aseptic loosening within five years.

A 90% two-sided confidence interval will be computed for the success rate at five years. If the lower bound of the confidence interval is greater than a 90% survival rate, then the non-inferiority hypothesis will be supported, that is the five-year success rate is non-inferior to 95% with a margin of 5%. If the lower bound of the confidence interval is greater than 95% then it is supported that the five-year success rate is superior to 95%.

The Kaplan-Meier survival curve of revision and removal of the Trident II Acetabular Shell for aseptic loosening will be displayed using SAS/PROC LIFETEST.

8.1.2 Secondary Objective Analyses

Radiographic stability will be tabulated for available visits.

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

8.2 Safety

8.2.1 Safety Parameters

Safety parameters include all protocol-defined adverse events as well as all-cause revision and/or removal of the Trident II Acetabular Shell. For details regarding protocol-defined adverse events, see **Section 6.1**.

8.2.2 Safety Analyses

The frequency and percentage of all protocol-defined adverse events will be tabulated. All protocol-defined adverse events will be tabulated and 95% confidence interval will be presented. For details regarding protocol-defined adverse events, see **Section 6.1**.

The Kaplan-Meier survival curve of all cause of revision and removal of the Trident II Acetabular Shell at ten years postoperative will be displayed.

8.3 Missing Data

No missing data will be imputed.

8.4 Statistical Methodology

8.4.1 Data Summary

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

For radiographic data, data will be presented according to visits for available parameters. Documentation of statistical analyses will be performed utilizing SAS® software version 9.1.3 or higher.

8.4.2 Sample Size Justification

Based on the literature review, it is reasonable to have a reference value of 95% of success rate at five years, and a case success at five years is defined as no incidence of revision and removal of Trident II Acetabular Shell for aseptic loosening within the five-year follow-up period. With the expectation that the success rate of Trident II Acetabular Shell for aseptic loosening within five years will be 94.5%, 277 cases will be needed to have a power of 95% to detect that the 5-year success rate is non-inferior to 95% with a margin of 5% at 5% significance level. After factoring a 20% lost to follow-up rate, a total of 347 cases will be needed.

8.4.3 Interim Analyses

No interim analysis is planned.

8.4.4 Analysis Population

Per Protocol Population: The study population for analysis will include all non-censored subjects who received the Trident II Acetabular Shell and are available for efficacy evaluation at the 5-year primary endpoint.

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

Safety Population: The safety population will include all non-censored subjects who received the Trident II Acetabular Shell.

The safety analysis will be based on the safety population.

9 Study Monitoring, Auditing, and Inspecting

9.1 Study Monitoring Plan

Monitors are persons employed by sponsors to review the conduct of clinical studies to assure that the clinical investigators abide by their obligations to conduct clinical studies properly. Proper monitoring ensures adequate protection of the rights of human subjects, the safety of subjects

involved in a clinical investigation and the quality and integrity of data submitted as a result of the investigation.

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

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

9.2 Auditing and Inspecting

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

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

10 Publication Plan

It is anticipated that publication of the multi-center study results will be compiled and submitted to a peer-reviewed journal at the time the study cohort reaches 5 and 10 years of follow-up. Early

results with regard to surgical information and postoperative functional outcomes may be published prior to the 5-year time point. Additional publication proposals may also be made by investigators at any time and will be considered.

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

At the completion of the study, each participating study investigator shall have independent publication privileges for his/her own center's results. These manuscripts and abstracts will be delayed until after the 5, and 10-year multi-center publications are submitted. Although Stryker will not be involved in coordinating these independent manuscripts, all publications of the data shall be submitted to Stryker for review prior to submission for publication. Stryker shall not edit or otherwise influence the publications other than to ensure that confidential information is not disclosed, that no off-label use of Stryker devices is promoted and that the data is accurately represented. Any publications resulting from this study must be submitted to Stryker for review at least 30 days prior to submission of publication.

11 Risk/Benefit Assessment

11.1 Risk Category

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

11.2 Potential Risk

The study involves the routine assessment of a revision THA procedure. The Trident II Acetabular Shells have been cleared for use by the FDA and will be used according to its labeling, included in **Appendix B**. Breach of data privacy is a known risk. All study assessments, patient and physician evaluations as well as radiographs will be kept confidential and will comply with the HIPAA privacy rule.

While the expected life of THA 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.

Risks associated with revision THA 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.

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

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

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

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

- Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum.

Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects or poor bone stock.

- Metal sensitivity reactions have been reported following joint replacement.

11.3 *Expected Complications*

Complications associated with THA procedures, such as those performed with the Trident II Acetabular Shells, have been reported. These include the potential for: injury to the hip's neurovascular structures, loosening of the components, malseating of the acetabular liner, heterotopic bone formation, infection, deep vein thrombosis, pulmonary embolism, metal sensitivity reactions, intraoperative or postoperative fracture of the femur or acetabulum, and the need for re-operation, revision, arthrodesis of the involved joint, girdlestone or amputation of the limb. Complication rates of the Trident II Acetabular Shells will be reviewed.

11.4 Protection Against Risks

Subjects will be treated in the best medical judgment of the investigator, regardless of the study protocol. If an investigator must deviate from the written protocol to protect the health or wellbeing of the subject, this deviation will be promptly reported to both the center's overseeing IRB and Stryker.

11.5 Potential Benefits to the Subject

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

12 Ethical Considerations

This study is to be conducted according to United States standards of GCPs and applicable government regulations including 21 CFR Parts 50 and 56, 45 CFR Parts 160 and 164, as well as ISO 14155.

This protocol and any amendments will be submitted to each investigative center's properly constituted independent IRB for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to Stryker before commencement of this study. The investigator may be asked to provide a list of IRB members and their affiliates to Stryker, if available.

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

13 Study Finances

13.1 Funding Source

This study is financed by Stryker.

13.2 Conflict of Interest

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

13.3 Subject Stipends or Payments

Subject attrition can occur for a variety of reasons, including a subject's loss of health insurance coverage. In a case where a patient has lost health insurance coverage and no other coverage is available, Stryker may, on a case-by-case basis, reimburse investigators for office visits and radiographic charges for subjects involved in this study in order to facilitate data retrieval. The

physician or the office staff should contact the fCSM prior to scheduling the subject to discuss this possibility and receive pre-approval. After receipt of the completed data forms, the physician must submit either evidence of coverage denial (e.g. explanation of benefits) or a letter explaining that the subject does not have insurance. Other visits, procedures and assessments done other than those specified in the protocol will not be reimbursed. Reimbursement may be provided under the following conditions:

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

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

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