THE ATX REGISTRY

ACCOLADE STEM & TRIDENT/TRITANIUM CUP WITH X3 INSERT

INTERNATIONAL MULTICENTRE SURVEILLANCE REGISTER

Protocol

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Version	Description	Changed by
Version 2.0 - 12JUL2012	Added Accolade II stem as a femoral option; Added Accolade II product description and References 22-24 Added Appendix IX Changed contact person for adverse events and surveillance monitoring to Chadi Aziz as actual study manager	Chadi Aziz Clinical Study Manager
Version 3.0 - 30AUG2013	Changed upper age limit in inclusion criteria 1 from 70 to 75 years of age Removed PTD visit from table in section 5, as PTD is not a separate visit Changed description of FU intervals in section 7 Changed email address and person to contact for SAE notifications as well as surveillance monitoring to Sietske Witvoet as actual study manager	Sietske Witvoet Clinic al Study Manager

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CLINICAL INVESTIGATION PLAN APPROVALS

According to CQP-SUP-003 Approval of Clinical Research Proposals, Protocols, Study Design Documents and Publications

TITLE: **ATX Registry**

Sub title: Accolade stem & Trident/Tritanium cup with X3 insert International Multicenter Surveillance Register

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THE ATX REGISTRY

ACCOLADE/ACCOLADE II STEM & TRIDENT/TRITANIUM CUP WITH X3 INSERT

INTERNATIONAL MULTICENTRE SURVEILLANCE REGISTER

PROTOCOL SUMMARY

- **Surveillance design**:

  International multicentre, prospective follow-up of a consecutive series of patients.

- **Objectives:**

  To verify the Accolade/Accolade II stem and Trident/Tritanium cup safety during follow-up and survivorship as described by Kaplan-Meier survival curves.

  To document the patient clinical outcome of the patients who are eligible for a hip arthroplasty surgery involving an Accolade/Accolade II stem and Trident/Tritanium cup.

- **Regulatory status of the device:**

  Name of the hip system: Accolade™ TMZF® hip stem. Accolade II stem. Trident and Tritanium cup and X3-liner. All components are CE-marked and approved for sale in Europe.

- **Participating institutions:**

  Each clinic need to recruit at least 20 patients and maximum 100 patients. Institutions willing to participate to the register and fulfilling the local and international applicable regulatory requirements can participate. Sufficient human and technical resources in the centre are expected to ensure optimal data collection.

- **Patients to be enrolled**:

  All patients eligible for a hip arthroplasty surgery involving the Accolade or Accolade II stem and Trident or Tritanium cup who have been informed about this surveillance register and who freely consent to participate will be enrolled in the register.

  Patients will be enrolled prospectively.

- **Clinical evaluations:**

  Adverse events/adverse events: All intra-operative and post-operative adverse events.

  Standard clinical parameters, Harris Hip Score, Oxford Hip Score and EQ5D will be registered preoperatively and at each follow-up visit.

ATX-REGISTRY
INTERNATIONAL MULTICENTRE SURVEILLANCE REGISTER

1 INTRODUCTION

Total hip replacement is one of the most common and successful techniques used in orthopaedic surgery. Alongside with cemented hip arthroplasties, cementless hip replacement has proven its value [1-6]. Still, the survival of hip implants is not indefinite. One of the causes for implant failure is loosening and osteolysis as a consequence of particulate wear or stress-shielding.

Many studies have investigated the factors that influence implant fixation and stability [7, 8]. Over the years knowledge on stability, fixation and preservation of bone stock has increased considerably. Also better understanding of joint kinematics allows designing implants with reduced joint reaction forces which again may lead to improved survival of implants. Stem designs have been changed accordingly. Important features in stem design are fit and fill, stem geometry, strain distribution, type and extent of coating [7-11]

Tapered stems, designed to provide mediolateral stability within the femoral canal, have had greater success. A clinical register in which 71 cases were implanted with a wedge fit, cobalt-chrome, cementless stem, resulted in a revision rate of 0% for aseptic loosening, and incidence of thigh pain of 1.4% at a minimum ten year follow-up.[12] This is lower than incidence of thigh pain at earlier visits, where it is reported to be 5% at two years follow-up. Decrease in thigh pain is seen with continuing follow-up. In a register conducted by Pellegrini et. al.[13] a 3.5% rate of thigh pain was reported at a mean follow-up 6.5 years (range five to eight years). Likewise, lower rates of thigh pain have been reported with similar tapered wedge fit designs: 4% by Hozack et al [14] and 6% by McLaughlin and Lee. [15] Conversely, higher rates of thigh pain have been reported with some uncemented femoral stems with different designs. Rates of thigh pain for different stem designs have been reported to be 9.4% by Engh and Massin [10], 15% by Heekin et al [17] and 20% by Maloney et al [18.] The superior results seen with the wedge fit stem can be partially attributed to excellent initial stability with subsequent bone in-growth.[12] It is likely that the tapered design allows for gradual transfer of stresses from the stem to the bone. Engineering analysis of the tapered design has been published which supports the stress transfer effect. [12, 13, 19]

The Stryker Accolade™ Femoral Component is a relatively new hip system constructed from a beta titanium alloy (TMZF®). The alloy can, which can offer 25% greater flexibility than standard Ti-6Al-4V, yielding a modulus that more closely approximates that of bone. In addition, this proprietary alloy maintains a 20% higher tensile strength than Ti-6Al-4V. Other features include a circumferential plasma spray over the proximal body that assists with mechanical engagement in bone and provides an optimum interface for fixation. Fixation is aided by a HA coating. (2 Pure Fix™) which is 50µm thick and has good mid to long term clinical results (10 years) in a multi-centre register.

Accolade II is the first Morphometric Wedge design, an evolution of the tapered wedge stem. The stem is uniquely designed with a size specific medial curvature to fit a broad range of bones sizes and shapes found in today's patient population (*Optimized length and fit based on a sample size of 556 CT scans)*.[22,23] Mechanical testing has shown this design facilitates initial press-fit stability[24] and load transmission in the proximal region of the femur.

The tapered wedge design of the Accolade TMZF and Accolade II Femoral Component provides firm mediolateral stability within the femoral canal. An offering of standard (132°) and extended (127°) offset options enhances soft tissue tensioning without significantly affecting leg length when adjusting joint stability. Furthermore, the TMZF alloy provides the opportunity to reduce the neck geometry thus optimizing the available range of motion while maintaining strength. The system is also designed for use with the V40™ femoral head with the associated range of offsets and neck lengths. Both forged Vitallium® alloy and zirconia ceramic heads can be used.

The aim of this register is to determine the Accolade/Accolade II stem and Trident/Tritanium cup survivorship over years.

2 SURVEILLANCE DESIGN

This is a prospective international multicentre surveillance register. The surveillance register will be conducted in accordance to the applicable regulatory requirements including local health data protection laws. Where applicable, Ethics Committees will be informed about the register and if required, Ethics Committee authorisation/favourable opinion will be asked prior to the register start.

All institutions willing to participate to the register, able to recruit at least 20 patients (up to 100 patients) and fulfilling the local and international applicable regulatory requirements can participate. Sufficient human and technical resources are expected in the institution to ensure optimal data collection. All patients eligible for a hip arthroplasty surgery involving the Accolade or Accolade II stem and Trident/Tritanium cup who have been informed about this surveillance register and who freely consent to participate will be enrolled in the register (written informed consent described in appendix 3 will be obtained from the patients).

3 OBJECTIVES & METHODS

- Safety & survivorship: All adverse events / failures or revision of the Accolade stem, Accolade II stem and Trident/Tritanium cup will be documented in order to draw Kaplan Meier survival curves of the Accolade stem and Trident/Tritanium cup over follow-up.
- Clinical outcome: Standard clinical parameters (Harris hip score, Oxford Hip Score and EQ5D) will be obtained to allow the surgeon to assess the clinical outcome of the patient.

The register will follow the standard clinical procedures used by the institutions for patient selection for hip arthroplasty surgery, patient surgery and patient follow-up. Therefore there will be, with regard to this register, no additional assessment, examination, procedure or follow-up visits compared to those usually performed in the institution (routine standard normal procedures).

4 SELECTION OF PATIENTS

4.1 Number of patients

Up to 1000 patients who received the Accolade or Accolade II stem and Trident/Tritanium cup with X3 liner can be enrolled into the ATX Surveillance Register.

4.2 Patient selection criteria

All patients in a participating centre matching all of the inclusion criteria and none of the exclusion criteria and who receive the Accolade or Accolade II stem and Trident/Tritanium cup with X3 liner will be recorded in the Register.

4.2.1 Inclusion criteria

Patients suitable for inclusion in the trial will be those fulfilling all the following selection criteria:

1. Male and non-pregnant female patients between 18-75 years of age.
2. Patients requiring uncemented primary THA, suitable for the use of the Accolade stem and Trident/Tritanium cup.
3. Patients with a diagnosis of osteoarthritis (OA).
4. Patients who understand the conditions of the study and are willing and able to comply with the post-operative scheduled clinical and radiographic evaluations and the prescribed rehabilitation.
5. Patients who signed the Ethics Committee approved Informed Consent Form prior to surgery.

4.2.2 Exclusion criteria

Patients with any of the following will be excluded from the trial:

1. Patients who require revision of a previously implanted hip prosthesis.
2. Patients who had a THA on contralateral side within the last 6 months.
3. Patients who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome was considered unsatisfactory or not good (Harris Hip Score < 85).
4. Patients who will need lower limb joint replacement for another joint within one year.
5. Patients requiring bilateral hip replacement.
6. Patients who have had a prior procedure of acetabular osteotomy.
7. Patients with acute femoral fractures
8. Obese patients where obesity is severe enough to affect subject's ability to perform activities of daily living (body mass index, kg/m^2: BMI ≥ 35).
9. Patients with active or suspected infection.
10. Patients with malignancy – active malignancy.
11. Patients with severe osteoporosis, rheumatoid arthritis (RA), Paget's disease or renal osteodystrophy.
12. Patients immunologically suppressed, or receiving steroids in excess of physiologic dose requirements.
13. The patient has a neuromuscular or neurosensory deficit which would limit the ability to assess the performance of the device or the patient has a neurological deficit which

interferes with the patient's ability to limit weight bearing or places an extreme load on the implant during the healing period.

14. Female patients planning a pregnancy during the course of the study.
15. Patients with systemic or metabolic disorders leading to progressive bone deterioration.
16. Patients, who as judged by the surgeon, are mentally incompetent or are unlikely to be compliant with the prescribed post-operative routine and follow-up evaluation schedule.
17. Patients with other severe concurrent joint involvements, which can affect their outcome.
18. Patients with other concurrent illnesses, which are likely to affect their outcome such as sickle cell anaemia, systemic lupus erythematosus or renal disease requiring dialysis.
19. Patient with a known sensitivity to device materials.
20. Patients under the protection of law (e.g. guardianship).

The patient will be informed by the Investigator (or his designated representative) of the purpose of the data collection. The patient will be informed that his/her medical records are subjected to review as necessary. The confidentiality of the patient will be maintained at all times and the collected data will be anonymous. The patient will be told that he/she is free to refuse the collection of his/her clinical data and to withdraw from the Surveillance at any time without compromising future medical care. A signed Patient Informed Consent will be obtained prior to patient participation (appendix 3).

5 LENGTH OF SURVEILLANCE AND VISIT SCHEDULE

The length of surveillance and patient visit schedule is based on the routine procedures of the institution. The surveillance system is set-up to record data at 1 year, 3 years, 5 years, 7 years and 10 years follow-up.

Visit schedule

VISIT	TIME WINDOW
Pre-op.	Date of or any time post the date of written informed consent up to 4 months prior to the date of surgery.
Operation	N/A
1 year post-op.	± 3 months
3 years post-op.	± 6 months
5 years post-op.	± 6 months
7 year post-op	± 6 months
10 years post-op.	± 6 months

6 DESCRIPTION OF THE DEVICES

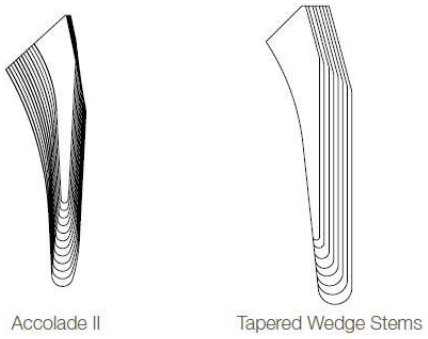
All components of the THA systems used in this Surveillance obtained the CE mark and are approved for sale and use throughout Europe.

6.1 Femoral Components

The Stryker Accolade™ TMZF® and Accolade II femoral stems are designed for the cementless total hip arthroplasty.

The Accolade® TMZF® is a single use stem intended for cementless fixation, to replace the proximal portion of the femur in primary total hip arthroplasty. The Accolade® TMZF® is a tapered wedge design, comprised of a proprietary beta titanium alloy. The proximal body is plasma sprayed providing an optimum interface for application of Pure Fix™ HA coating. The bone sparing design accommodates either a small or standard size incision or a variety of approaches. There are two neck angles available, the standard 132° and the extended 127°. There are 13 stem sizes available, 9 full sizes (0-8) and 4 half sizes (2.5, 3.5, 4.5, 5.5), for each neck angle. The additional half sizes were developed to accommodate differences in patient anatomy. (See Appendix IV for the device description details).

The Accolade II stem is a morphometric taper wedge design with a size specific medial curvature (see illustration below).



The following table shows the comparison between the Accolade and Accolade II designs and main features:

	Accolade	Accolade II
Medial curvature	• Constant	• Variable
Stem Length	• 110 -146	• 92 -125
Neck finish	• Satin	• Polished
Material	• TMZF	• Ti6Al4V
Tapered design	• 6° A/P Taper • 3° M/L Taper	• 6° A/P Taper • 3° M/L Taper
Coating	• Ti Plasma Spray • PureFix HA	• Ti Plasma Spray • PureFix HA
Neck Angle	• 127 & 132	• 127 & 132
Neck Lengths	• 30, 35, 37, 40	• 27, 30, 35, 37, 40

There are 12 stem sizes for Accolade II (size 0 to 11) for each neck angle. (Please refer to Appendix IX for more Accolade II detailed information)

6.2 Acetabular Component

As Acetabular component either Trident or Trident Tritanium can be used.

Trident®

The Trident™ family of products provides a range of acetabular shells to help surgeons choose the right shell and bearing option for the patient in question. These include PSL or Hemispherical, HA (PureFix™ HA) or non HA coated cups and no hole, cluster hole or multi hole options.

The Trident™ Hemispherical shells are available in sizes 42mm-70mm. The Trident™ PSL shells are available in sizes 40mm-68mm. They can be used with:

- X3™ polyethylene inserts 0°, 10°, excentric, elevated rim, or constrained, in sizes 22mm-44mm (depending on type of insert), for use with either a CoCr, LFIT™ CoCr, Alumina

- Ceramic, BIOLOX *delta* Ceramic, or Orthinox™ head and Alumina inserts 0° in sizes 28mm-36mm, for use with either a Alumina Ceramic or BIOLOX *delta* Ceramic head. **Please note, in this surveillance registry ONLY X3 liner is approved!**

TridentTritanium™

TridentTritanium™Acetabular System provides surgeons with a highly porous ingrowth surface.

TridentTritanium™Acetabular System hemispherical shells are manufactured from Commercially Pure Titanium. The TridentTritanium™ shells utilize the screw hole pattern and locking mechanism from the TridentAcetabular system. TridentTritanium™ Hemispherical comes as solid back shells (no holes), cluster shells and multi-hole shells.
The hemispherical shells are available in sizes 44mm-72mm to be used with X3™ polyethylene inserts 0° (in sizes 22mm-44mm), 10° (in sizes 22mm-36mm) or with elevated rim (in sizes 28mm-36mm). The inserts are provided for either a CoCr, LFIT™ CoCr, Alumina Ceramic, BIOLOX *delta* Ceramic, or Orthinox™ heads. **Please note that in this surveillance registry ONLY X3 liners are approved!**

7 PATIENT EVALUATIONS

Patients will be assessed pre-operatively, per-operatively and post-operatively. The follow-up intervals will be as specified in section 5.

7.1 Evaluations at each assessment

7.1.1 Pre-operative Evaluation

- Clinical History

- Patient ID (Study,Site,Subject)
- Date of birth, weight height, Gender
- Visit Date
- Cigarette and Alcohol use
- Charnley patient category
- Privious surgery to hip planned for operation
- Primary Diagnosis

- Clinical Evaluation

- Patient ID (Study,Site,Subject)
- Operative site
- Date of informed consent signed
- Inclusion/ Exclusion
- Harris Hip Score Evaluation
- Oxford Hip Score
- EQ5D

7.1.2 Intra-operative Evaluation

- Surgical details

- Surgery Date
- Operative Side
- Surgical approach
- Minimally invasive surgery and size of incision
- Anaesthesia class and type
- Duration of surgery
- Intra-operative adverse events
- Components used and sizes
  - Solid back / Cluster shells and Multi-hole shells
- Systemic antibiotic prophylaxis
- NSAIDs

7.1.3 Post-operative Evaluation

Patients will be assessed post operatively as per the visit schedule in section 5.

- Clinical Evaluation

- Date of assessment
- Adverse events
- Harris Hip Score Evaluation
- Oxford Hip Score
- EQ5D

7.1.4 Adverse events and device removal events

- Onset date
- When Did the event occur (Intra-op, Post-op)
- Operative site events
- Systemic events
- Device related
- Seriousness
- Treatment
    - Revision/Removal
    - Reoperations
    - Other treatment
- Resolution of event

7.1.5 Termination

- Date of termination of Surveillance
- Date of last visit assessment
- Reason for termination

8 ADVERSE EVENTS

The investigator is required to document all operative site and general medical adverse events, including date of occurrence, date diagnosed, type of complication and treatment.

8.1 Definitions

8.1.1 Adverse event

An **adverse event** is “any unfavourable and intended sign, symptom or illness that develops or worsens during the period of observation in the Register. This definition does not imply that there is a relationship between the adverse event and the device under investigation.” [21]

Surgical procedures themselves are not adverse events; they are therapeutic measures for conditions that require surgery. The condition for which the surgery is required is an adverse event, if it occurs or is detected during the Register follow-up period.

A **serious adverse event** is an adverse event which

a) led to a death

b) led to a serious deterioration in the health of a subject that

1. resulted in a life-threatening illness or injury
2. resulted in a permanent impairment of a body structure or a body function
3. required in-patient hospitalization or prolongation of existing hospitalisation
4. resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function

c) led to foetal distress, foetal death or a congenital abnormality or birth defect

8.1.2 Adverse device effect

An **adverse device effect** is "any untoward and unintended response to a medical device (this definition includes any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device. This definition includes any event that is a result of a user error)". [21]

A **serious adverse device effect** is "an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune"

8.2 Documentation and reporting of adverse event by the investigator

All subjects who have adverse events, whether considered associated with the use of the implant or not, must be monitored to determine the outcome.

The assessment of the causal relationship between the adverse event and the device will be reported by the surgeon as:

- definitively
- probably
- possibly
- probably not
- definitively not

All serious adverse events, serious adverse device effect, adverse device effects and unexpected adverse events, in accordance with the above definitions, must be reported to the sponsor **within 24 hours** from their occurrence, using the *adverse event report form.* Written and detailed subsequent follow-up reports will be provided to the sponsor.

A Serious Adverse Event report form should be completed by the investigator and sent by email (AE.Clinical@stryker.com) to the sponsor, **within 24 hours.** If at the time of sending the report, all details are not available by the investigator; this one must send it with the available data and then seek to obtain complementary information. The complementary information will be sent by the investigator to the sponsor as soon as it will be available.

Please contact your local Stryker Clinical contact, or the study manager for any adverse events.

In addition, all adverse events, serious or not, occurring between two planned visits will be reported in the CRF.
Death will be both reported in the *serious adverse event report form* and in the *termination form* part of the CRF.

Moreover the investigator should send to the Sponsor a copy of the imaging exam when performed at the time of the adverse event.
The investigator will evaluate the adverse event and determine the most appropriate actions.
The sponsor will report to Competent Authorities and Ethic Committees adverse events occurred during the study in accordance with applicable regulations.

9 PATIENT WITHDRAWALS

Patients are free to withdraw from the Surveillance at any time and are under no obligation to provide a reason for doing so. Patients who withdraw from the Surveillance should have the reason for their withdrawal recorded on the case report forms (CRF's), if at all possible. All attempts should be made to ascertain whether any patient apparently lost to follow up has actually chosen not to return or is deceased.

10 ELECTRONIC DATA CAPTURE: eCRF

All the above-mentioned pre-operative patient assessments, intra-operative details and post-operative follow-up assessments will be recorded on a CRF (Case Report Forms) which will be provided to any centre being part of the ATX Register.

The CRF will be provided electronically (secured electronic data capture:EDC). A patient blank paper case report form can be printed by surgeons wishing data collection on paper before data entry in the EDC. After EDC data entry, a hard copy can be printed as well for each patient by the surgeon(s). This EDC system (NetRegulus RM) complies with the FDA and international requirements for electronic database(s) security and performances.

The system will be secured to prevent unauthorized access to the data or to the system by using the combination of user ID and password which will be provided by Stryker SA to the authorised users of each centre. The investigator will maintain a list of individuals who are authorized to enter or correct data in the system.

The surgeon and his/her other defined users will receive system documentation, training and support for the use of the EDC. All required information collected during the following period must be entered by the investigator or designated representative in the EDC. All data entry, modification or deletion will be recorded automatically in an electronic audit trail (tracking of the data entered or modified). The combination of both user ID and password will correspond to the surgeon electronic signature which will be required for patient data validation.

The secured database will be physically hosted by Stryker Orthopaedics Mahwah, New Jersey (US).

Strict confidentiality and anonymity will be applied: only the subject number will be recorded in the database.

The investigator will maintain a personal subject identification list (subject numbers with the corresponding subject names) to enable records to be identified.

11 SURVEILLANCE MONITORING

During the course of the ATX Registry and thereafter until the centre has been closed, the monitor(s) possibly visit the Centre(s) recruiting patients into the Registry by prior arrangement. The clinical Study manager or monitor can also be contacted concerning any problems or queries regarding the clinical ATX Registry.

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The monitor shall be given unhindered access to monitor relevant source documents (including medical records) to enable complete data verification, but with respect to the patient's integrity as described in section 17.4.

12 ANALYSIS OF RESULTS

Results obtained from the ATX Registry will be tabulated and statistically analysed by Stryker's Clinical Research Department using an appropriate statistical software package. An interim analysis of the data will be made once appropriate patients are included in the Registry.

12.1 Statistical Analysis

The main aim of the register is to document the patient's safety and survivorship of the Accolade stem and Trident/Tritanium cup during the follow-up. The main failure item to be considered for Kaplan-Meier survival curves is surgical revision of the Accolade stem or Trident/Tritanium cup but all other adverse events types can be separately considered as failures for Kaplan-Meier survival curve assessment.

In addition to the Kaplan Meier survival curves, the surgeons involved in the register will have the possibility to analyse the following statistical descriptions/comparisons:

- Demographic and pre-operative assessments
- Intra-operative assessments
- Post-operative pain and function assessments: Harris Hip Score.
- Oxford Hip Score
- Quality of Life assessments: EQ5D
- Adverse events and device-related adverse events
- Revisions/removals

Frequency and percent distributions will be presented in tabular form for categorical variables. The mean, standard deviation, minimum and maximum values will be presented for quantitative variables.

13 PUBLICATION OF RESULTS

By signing the protocol, the investigator agrees to the results of the study being used for publication and for informing medical and pharmaceutical professionals. If necessary, names, addresses, qualifications and the role of the investigator in the study shall be notified to the authorities.

The sponsor shall compile a final study report.

The co-ordinating investigator and the principal investigators at each centre must confirm, by their signature, that they have read the report. They must confirm that to their knowledge, the report describes the study results, and the way in which it has been conducted, accurately.

The method and timetable for compiling the publications shall be defined by mutual agreement between the Sponsor and the Investigators.

14 RISK BENEFIT ANALYSIS

14.1 Risk

As in any surgical procedure, certain risks are associated with total joint arthroplasty. These risks include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves, trochanteric or femoral fractures during implantation, perforation of the cortical wall, or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication.

14.2 Minimization of Risks

Pre-clinical, clinical, and mechanical testing of the Stryker Accolade® TMZF® Hip Stem, the Accolade II stem and Trident/Tritanium cup indicate that the above mentioned risks should not occur at a rate greater than that for any other type of total hip arthroplasty reported in the literature.

14.3 Benefit

Patient benefits should include relief of pain and increase in functional capabilities, in addition to better assessment of the effect of prosthesis design and materials on functional and radiographic performance and bone remodelling around cementless femoral prostheses. This will increase the current scientific body of knowledge concerning total hip arthroplasty.

15 ETHICAL CONSIDERATIONS

15.1 Declaration of Helsinki

The Surveillance will follow the guidelines as laid down by the "Declaration of Helsinki" (Declaration of Helsinki, October 2008) (see Appendix II).

In accordance with the Declaration of Helsinki, where applicable, all centres will gain written Ethics Committee approval prior to enrolling patients in the Surveillance. Ethics Committee approval for the data collection must be gained either from the local responsible Ethics Committee at the investigator site or from an adequately constituted (according to ISO14155-1: 2003) independent Ethics Committee.

15.2 Informed Consent

All recruited patients will sign and date the informed consent form before any investigational procedure or visit is performed. Only the latest ethics committee approved version is a valid document. The patient is provided with a copy of the information letter and consent form. The investigator is acquainted with the contents of the information sheet and answers patient questions regarding participation in the study.

15.3 Patient Insurance (product liability)

Participating patients in this Surveillance are covered by Stryker SA product liability insurance.

15.4 Personal data protection

Stryker SA affirms and upholds the principle of the patient rights to protection against invasion of privacy. All data recorded in the CRFs or used for further evaluation are coded by patient number and age. Identification is restricted to authorized persons. In all data analyses the identity of patients will remain anonymous. Anonymous patient data may be stored and electronically processed by Stryker Europe for the purpose of scientific evaluation and may be forwarded to a company and/or an authority located in- and outside Europe for registration and/or marketing purposes. Only authorized representatives of Stryker Europe and health authorities will have allowed access to personal medical records for the sole purpose of checking the accuracy of data collected in the trial.

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APPENDIX I

DECLARATION OF HELSINKI WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens. DoH 2/Oct2008

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

B. PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research register involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research register. The protocol should describe arrangements for post-register access by register subjects to interventions identified as beneficial in the register or access to other appropriate care or benefits.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the register begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse

events. No change to the protocol may be made without consideration and approval by the committee.

16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy DoH3/Oct2008 volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

18. Every medical research register involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research register involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a register when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research register unless he or she freely agrees.

23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the register on their physical, mental and social integrity.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the register and the discomfort it may entail, and any other relevant aspects of the register. The potential subject must be informed of the right to refuse to participate in the register or to withdraw consent to participate at any time

without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. DoH/Oct2008

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research register the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research register that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the register may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the register has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results

should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication. DoH/Oct2008

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research register will not adversely affect the health of the patients who serve as research subjects.

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
• The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
• Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the register, patients entered into the register are entitled to be informed about the outcome of the register and to share any benefits that result from it, for example, access to interventions identified as beneficial in the register or to other appropriate care or benefits.

34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a register or the patient's decision to withdraw from the register must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

APPENDIX II

ATX REGISTER

PATIENT INFORMATION SHEET AND INFORMED CONSENT

My surgeon informed me that he is participating in collaboration with Stryker SA, the manufacturer of my hip prosthesis, to a surveillance register of the Accolade hip prosthesis in combination with Trident and Tritanium uncemented cup in order to document the long term safety and survivorship of these implants. I've understood that many patients from different European hospitals/clinics will freely take part in this register. I also understood that there will be no additional assessment/questionnaires or clinical visits for this register compared to the usual clinical practice required for the follow-up of my hip in the hospital/clinic where I have been operated.

I agree that Stryker SA, the manufacturer of my new hip, receives my anonymous coded clinical information which is related to my new hip. I understand that this hip underwent some developments and that my clinical data is used to confirm the safety and efficacy of the implant. I understand that my clinical data collected during the surveillance register is recorded electronically in a secured database and also possibly on paper, and that access is limited to only a few authorized persons. I agree that my clinical information is possibly used for publications and that I will never be recognized in such a publication.

I understand that my participation is voluntary and that at any time I can refuse that new information will be recorded without affecting the received quality of care.

Patient name ……..

Signature …… Date …….

Surgeon name ……

Signature …… Date …….

OPTIONAL

Witness name (optional) …….

Signature …… Date …….
Relative/ Representative/Other

APPENDIX III

INVESTIGATOR AGREEMENT

ATX REGISTER
SURGEON AGREEMENT

I have read and understood the ATX Register procedures stated in this document and I agree to conduct the Register according to its contents.

NAME OF SURGEON :

NAME OF REGISTER CENTRE:

ADDRESS OF REGISTER CENTRE:

……...

……...

……...

……...

……...

……...

……...

SIGNATURE:

DATE:

APPENDIX IV

ACCOLADE COMPONENT SIZES

Accolade TMZF Cementless Femoral Stem (127° Neck Angle)

Catalog Number	Stem Size	Stem Length (from Medial Calcar)	Neck Length	Offset (+0mm)
6021-0030*	0	86mm	30mm	37mm
6021-0130	1	110mm	30mm	38mm
6021-0230	2	115mm	30mm	39mm
6021-2530	2.5	118mm	30mm	40mm
6021-0335	3	120mm	35mm	43mm
6021-3535	3.5	124mm	35mm	43mm
6021-0435	4	125mm	35mm	44mm
6021-4535	4.5	129mm	35mm	45mm
6021-0537	5	130mm	37mm	48mm
6021-5537	5.5	133mm	37mm	49mm
6021-0637	6	135mm	37mm	49mm
6021-0740	7	140mm	40mm	53mm
6021-0840	8	145mm	40mm	54mm

Accolade TMZF Cementless Femoral Stem (132° Neck Angle)

Catalog Number	Stem Size	Stem Length (from Medial Calcar)	Neck Length	Offset (+0mm)
6020-0030*	0	86mm	30mm	33mm
6020-0130	1	110mm	30mm	34mm
6020-0230	2	115mm	30mm	35mm
6020-2530	2.5	118mm	30mm	36mm
6020-0335	3	120mm	35mm	39mm
6020-3535	3.5	124mm	35mm	39mm
6020-0435	4	125mm	35mm	40mm
6020-4535	4.5	129mm	35mm	41mm
6020-0537	5	130mm	37mm	44mm
6020-5537	5.5	133mm	37mm	45mm
6020-0637	6	135mm	37mm	45mm
6020-0740	7	140mm	40mm	48mm
6020-0840	8	145mm	40mm	49mm

*Available by request.

APPENDIX V

TRIDENT COMPONENT SIZES

Trident Hemispherical Cluster Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Screw Holes	Window Trial Catalog No.
502-01-42A	42	42	3	2208-2042A
502-01-44B	44	44	3	2208-2044A
502-01-46C	46	46	3	2208-2046A
502-01-48D	48	48	3	2208-2048A
502-01-50D	50	50	3	2208-2050A
502-01-52E	52	52	5	2208-2052A
502-01-54E	54	54	5	2208-2054A
502-01-56F	56	56	5	2208-2056A
502-01-58F	58	58	5	2208-2058A
502-01-60G	60	60	5	2208-2060A
502-01-62G	62	62	5	2208-2062A
502-01-64H	64	64	5	2208-2064A
502-01-66H	66	66	5	2208-2066A
502-01-68I	68	68	5	2208-2068A
502-01-70I	70	70	5	2208-2070A
502-01-72J	72	72	5	2208-2072A
502-01-74J	74	74	5	2208-2074A

Trident Hemispherical HA Cluster Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Screw Holes	Window Trial Catalog No.
502-11-42A	42	42	3	2208-2042A
502-11-44B	44	44	5	2208-2044A
502-11-46C	46	46	5	2208-2046A
502-11-48D	48	48	5	2208-2048A
502-11-50D	50	50	5	2208-2050A
502-11-52E	52	52	5	2208-2052A
502-11-54E	54	54	5	2208-2054A
502-11-56F	56	56	5	2208-2056A
502-11-58F	58	58	5	2208-2058A
502-11-60G	60	60	5	2208-2060A
502-11-62G	62	62	5	2208-2062A
502-11-64H	64	64	5	2208-2064A
502-11-66H	66	66	5	2208-2066A
502-11-68I	68	68	5	2208-2068A
502-11-70I	70	70	5	2208-2070A
502-11-72J	72	72	5	2208-2072A
502-11-74J	74	74	5	2208-2074A

Trident Hemispherical Solid Back Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Window Trial Catalog No.
500-01-42A	42	42	2208-2042A
500-01-44B	44	44	2208-2044A
500-01-46C	46	46	2208-2046A
500-01-48D	48	48	2208-2048A
500-01-50D	50	50	2208-2050A
500-01-52E	52	52	2208-2052A
500-01-54E	54	54	2208-2054A
500-01-56F	56	56	2208-2056A
500-01-58F	58	58	2208-2058A
500-01-60G	60	60	2208-2060A
500-01-62G	62	62	2208-2062A
500-01-64H	64	64	2208-2064A
500-01-66H	66	66	2208-2066A
500-01-68I	68	68	2208-2068A
500-01-70I	70	70	2208-2070A
500-01-72J	72	72	2208-2072A
500-01-74J	74	74	2208-2074A

Trident Hemispherical HA Solid Back Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Window Trial Catalog No.
500-11-42A	42	42	2208-2042A
500-11-44B	44	44	2208-2044A
500-11-46C	46	46	2208-2046A
500-11-48D	48	48	2208-2048A
500-11-50D	50	50	2208-2050A
500-11-52E	52	52	2208-2052A
500-11-54E	54	54	2208-2054A
500-11-56F	56	56	2208-2056A
500-11-58F	58	58	2208-2058A
500-11-60G	60	60	2208-2060A
500-11-62G	62	62	2208-2062A
500-11-64H	64	64	2208-2064A
500-11-66H	66	66	2208-2066A
500-11-68I	68	68	2208-2068A
500-11-70I	70	70	2208-2070A
500-11-72J	72	72	2208-2072A
500-11-74J	74	74	2208-2074A

Trident PSL HA Solid Back Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Window Trial Catalog No.
540-11-40A	40	41.8	2208-2040A
540-11-42B	42	43.8	2208-2042A
540-11-44C	44	45.8	2208-2044A
540-11-46D	46	47.8	2208-2046A
540-11-48D	48	49.8	2208-2048A
540-11-50E	50	51.8	2208-2050A
540-11-52E	52	53.8	2208-2052A
540-11-54F	54	55.8	2208-2054A
540-11-56F	56	57.8	2208-2056A
540-11-58G	58	59.8	2208-2058A
540-11-60G	60	61.8	2208-2060A
540-11-62H	62	63.8	2208-2062A
540-11-64H	64	65.8	2208-2064A
540-11-66I	66	67.8	2208-2066A
540-11-68I	68	69.8	2208-2068A
540-11-70J	70	71.8	2208-2070A
540-11-72J	72	73.8	2208-2072A

Trident PSL HA Cluster Shells

Implant Catalog No.	Shell Size (mm)	Rim Dia. (mm)	Screw Holes	Window Trial Catalog No.
542-11-40A	40	41.8	3	2208-2040A
542-11-42B	42	43.8	3	2208-2042A
542-11-44C	44	45.8	3	2208-2044A
542-11-46D	46	47.8	3	2208-2046A
542-11-48D	48	49.8	3	2208-2048A
542-11-50E	50	51.8	5	2208-2050A
542-11-52E	52	53.8	5	2208-2052A
542-11-54F	54	55.8	5	2208-2054A
542-11-56F	56	57.8	5	2208-2056A
542-11-58G	58	59.8	5	2208-2058A
542-11-60G	60	61.8	5	2208-2060A
542-11-62H	62	63.8	5	2208-2062A
542-11-64H	64	65.8	5	2208-2064A
542-11-66I	66	67.8	5	2208-2066A
542-11-68I	68	69.8	5	2208-2068A
542-11-70J	70	71.8	5	2208-2070A
542-11-72J	72	73.8	5	2208-2072A

APPENDIX VI

TRITANIUM COMPONENT SIZES

Tritanium Primary Hemispherical Solid Back Shell

Catalog No.	Shell Size (mm)	Rim Diameter (mm)
500-03-44A	44	44
500-03-46B	46	46
500-03-48C	48	48
500-03-50D	50	50
500-03-52D	52	52
500-03-54E	54	54
500-03-56E	56	56
500-03-58F	58	58
500-03-60F	60	60
500-03-62G	62	62
500-03-64G	64	64
500-03-66H	66	66

Tritanium Primary Hemispherical Cluster Hole Shell

Catalog No.	Shell Size (mm)	Rim Diameter (mm)
502-03-44A	44	44
502-03-46B	46	46
502-03-48C	48	48
502-03-50D	50	50
502-03-52D	52	52
502-03-54E	54	54
502-03-56E	56	56
502-03-58F	58	58
502-03-60F	60	60
502-03-62G	62	62
502-03-64G	64	64
502-03-66H	66	66

APPENDIX VII

X3 COMPONENT SIZES

Trident® X3™ Polyethylene Inserts

• Assembles into all Trident® Acetabular Shells

	X3™ Implants			Shell Compatibility		
Alpha Code	0° Catalog No.	10° Catalog No.	ID (mm)	Trident® **PSL®** HA Shell Size (mm)	Trident® **Hemispherical** Shell Size (mm)	Poly Thickness (mm)
A	623-00-22A	623-10-22A	22	40	42	7.8
B	623-00-22B	623-10-22B	22	42	44	8.8
C	623-00-22C	623-10-22C	22	44	46	9.8
D	623-00-22D	623-10-22D	22	46, 48	48, 50	10.8
E	623-00-22E	623-10-22E	22	50, 52	52, 54	12.8
F	623-00-22F	623-10-22F	22	54, 56	56, 58	14.8
G	623-00-22G	623-10-22G	22	58, 60	60, 62	16.3
H	623-00-22H	623-10-22H	22	62, 64	64, 66	18.1
I	623-00-22I	623-10-22I	22	66, 68	68, 70	19.6
J	623-00-22J	623-10-22J	22	70, 72	72, 74	21.6
C	623-00-26C	623-10-26C	26	44	46	7.9
D	623-00-26D	623-10-26D	26	46, 48	48, 50	8.9
E	623-00-26E	623-10-26E	26	50, 52	52, 54	10.9
F	623-00-26F	623-10-26F	26	54, 56	56, 58	12.9
G	623-00-26G	623-10-26G	26	58, 60	60, 62	14.4
H	623-00-26H	623-10-26H	26	62, 64	64, 66	16.2
I	623-00-26I	623-10-26I	26	66, 68	68, 70	17.7
J	623-00-26J	623-10-26J	26	70, 72	72, 74	19.7
C	623-00-28C	623-10-28C	28	44	46	5.9
D	623-00-28D	623-10-28D	28	46, 48	48, 50	7.9
E	623-00-28E	623-10-28E	28	50, 52	52, 54	9.9
F	623-00-28F	623-10-28F	28	54, 56	56, 58	11.9
G	623-00-28G	623-10-28G	28	58, 60	60, 62	13.4
H	623-00-28H	623-10-28H	28	62, 64	64, 66	15.2
I	623-00-28I	623-10-28I	28	66, 68	68, 70	16.7
J	623-00-28J	623-10-28J	28	70, 72	72, 74	18.7
D	623-00-32D	623-10-32D	32	46, 48	48, 50	5.9
E	623-00-32E	623-10-32E	32	50, 52	52, 54	7.9
F	623-00-32F	623-10-32F	32	54, 56	56, 58	9.9
G	623-00-32G	623-10-32G	32	58, 60	60, 62	11.4
H	623-00-32H	623-10-32H	32	62, 64	64, 66	13.2
I	623-00-32I	623-10-32I	32	66, 68	68, 70	14.7
J	623-00-32J	623-10-32J	32	70, 72	72, 74	16.7
E	623-00-36E	623-10-36E	36	50, 52	52, 54	5.9
F	623-00-36F	623-10-36F	36	54, 56	56, 58	7.9
G	623-00-36G	623-10-36G	36	58, 60	60, 62	9.4
H	623-00-36H	623-10-36H	36	62, 64	64, 66	11.2
I	623-00-36I	623-10-36I	36	66, 68	68, 70	12.7
J	623-00-36J	623-10-36J	36	70, 72	72, 74	14.7

0°

Trident® X3™ Eccentric Inserts

- Assembles into all Trident® Acetabular Shells
- Head center is lateralized 6mm from Trident® shell center

	Eccentric Implants			Shell Compatibility		
Alpha Code	0° Catalog No.	10° Catalog No.	ID (mm)	Trident® **PSL® HA** Shell Size (mm)	Trident® **Hemispherical** Shell Size (mm)	Poly Thickness (mm)
B	663-00-28B	N/A	28	42	44	9.6
C	663-00-28C	663-10-28C	28	44	46	10.5
D	663-00-28D	663-10-28D	28	46, 48	48, 50	11.6
E	663-00-28E	663-10-28E	28	50, 52	52, 54	13.5
F	663-00-28F	663-10-28F	28	54, 56	56 ,58	15.6
G	663-00-28G	663-10-28G	28	58, 60	60, 62	17.1
H	663-00-28H	663-10-28H	28	62, 64	64, 66	18.8
I	663-00-28I	663-10-28I	28	66, 68	68, 70	20.4
J	663-00-28J	663-10-28J	28	70, 72	72, 74	22.4
D	663-00-32D	663-10-32D	32	46, 48	48, 50	9.5
E	663-00-32E	663-10-32E	32	50, 52	52, 54	11.5
F	663-00-32F	663-10-32F	32	54, 56	56, 58	13.5
G	663-00-32G	663-10-32G	32	58, 60	60, 62	15.0
H	663-00-32H	663-10-32H	32	62, 64	64, 66	16.8
I	663-00-32I	663-10-32I	32	66, 68	68, 70	18.3
J	663-00-32J	663-10-32J	32	70, 72	72, 74	20.3

APPENDIX VIII

HEAD COMPONENT SIZES

V40 Delta Ceramic Head	mm	Offset
6570-0-028	28	-4
6570-0-328	28	-2.7
6570-0-128	28	0
6570-0-228	28	+4
6570-0-032	32	-4
6570-0-132	32	0
6570-0-232	32	+4
6570-0-036	36	-5
6570-0-436	36	-2.5
6570-0-136	36	0
6570-0-536	36	+2.5
6570-0-236	36	+5
6570-0-736	36	+7.5

Universal Taper Biolox Delta Ceramic Head	mm	Offset
6519-1-028	28	+0
6519-1-032	32	+0
6519-1-036	36	+0
6519-1-040	40	+0
6519-1-044	44	+0

Universal Adapter sleeves	offset
6519-T-025	-2.5
6519-T-100	+0
6519-T-204	+4

V40 LFIT CoCr Head	mm	off set
6260-9-122	22	+0
6260-9-222	22	+3
6260-9-322	22	+8
6260-9-026	26	-3
6260-9-126	26	+0
6260-9-226	26	+4
6260-9-326	26	+8
6260-9-426	26	+12
6260-9-028	28	-4
6260-9-128	28	+0
6260-9-228	28	+4
6260-9-628	28	+6
6260-9-328	28	+8
6260-9-428	28	+12
6260-9-032	32	-4
6260-9-132	32	+0
6260-9-232	32	+4
6260-9-332	32	+8
6260-9-432	32	+12
6260-9-036	36	-5
6260-8-036	36	-4

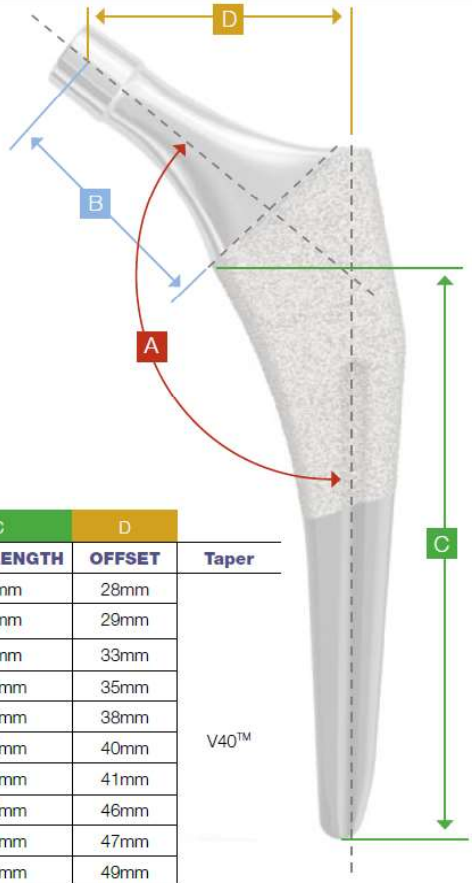
6260-9-136	36	+0
6260-8-236	36	+4
6260-9-236	36	+5
6260-8-336	36	+8
6260-9-336	36	+10
6260-9-040	40	-4
6260-9-140	40	+0
6260-9-240	40	+4
6260-9-340	40	+8
6260-9-440	40	+12
6260-9-044	44	-4
6260-9-144	44	+0
6260-9-244	44	+4
6260-9-344	44	+8
6260-9-444	44	+12

V40 Vitallium CoCr Head	mm	Offset
6260-4-122	22	+0
6260-4-222	22	+3
6260-4-322	22	+8
6260-5-026	26	-3
6260-5-126	26	+0
6260-5-226	26	+4
6260-5-326	26	+8
6260-5-426	26	+12
6260-5-028	28	-4
6260-5-128	28	+0
6260-5-228	28	+4
6260-5-628	28	+6
6260-5-328	28	+8
6260-5-428	28	+12
6260-5-032	32	-4
6260-5-132	32	+0
6260-5-232	32	+4
6260-5-332	32	+8
6260-5-432	32	+12

V40 Alumina head	mm	Offset
6565-0-028	28	-2.7
6565-0-128	28	+0
6565-0-228	28	+4
6565-0-032	32	-4
6565-0-132	32	+0
6565-0-232	32	+4
6565-0-036	36	-5
6565-0-136	36	+0
6565-0-236	36	+5

APPENDIX IX

ACCOLADE II COMPONENT SIZES



		A	B	C	D	
PART NUMBER	**SIZE**	**NECK ANGLE**	**NECK LENGTH**	**STEM LENGTH**	**OFFSET**	**Taper**
6720-0027	0	132°	27mm	93mm	28mm	V40™
6720-0127	1		27mm	96mm	29mm	
6720-0230	2		30mm	99mm	33mm	
6720-0330	3		30mm	102mm	35mm	
6720-0435	4		35mm	105mm	38mm	
6720-0535	5		35mm	108mm	40mm	
6720-0635	6		35mm	111mm	41mm	
6720-0737	7		37mm	114mm	46mm	
6720-0837	8		37mm	117mm	47mm	
6720-0937	9		37mm	120mm	49mm	
6720-1040	10		40mm	123mm	51mm	
6720-1140	11		40mm	126mm	53mm	

6721-0027	0	127°	27mm	93mm	32mm	V40™
6721-0127	1		27mm	96mm	34mm	
6721-0230	2		30mm	99mm	37mm	
6721-0330	3		30mm	102mm	38mm	
6721-0435	4		35mm	105mm	42mm	
6721-0535	5		35mm	108mm	44mm	
6721-0635	6		35mm	111mm	45mm	
6721-0737	7		37mm	114mm	50mm	
6721-0837	8		37mm	117mm	51mm	
6721-0937	9		37mm	120mm	53mm	
6721-1040	10		40mm	123mm	57mm	
6721-1140	11		40mm	126mm	58mm	