

# The ATX registry

<b>Submission date</b> 20/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/01/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Total hip replacement is one of the most common and successful techniques used in orthopaedic surgery. Along with cemented hip replacements, cementless hip replacement has proven its value. Still, the survival of hip implants is not indefinite. Over the years knowledge on stability, fixation and preservation of bone stock has increased considerably. Better understanding of joint movement also allow us to design implants with reduced joint reaction forces, which again may lead to improved survival of implants. The Stryker Accolade™ Femoral Component is a relatively new hip system constructed from a beta titanium alloy (TMZF®). The alloy, which can offer greater flexibility and higher tensile strength than standard titanium alloys, has an elasticity modulus (stiffness) that is closer to that of bone. The upper half of the stem is coated with a hydroxyapatite (HA) coating, which assists in bone ingrowth and provides a good interface for fixation of the stem. The Accolade II stem is an evolution of the Accolade TMZF stem. The size-specific fit of the stem has been redesigned to fit a broad range of bones sizes and shapes found in todays patient population. The aim of this study is to determine the safety and survivorship of the Accolade/Accolade II stem and the Trident/Tritanium cup over 10 years and to document the patients clinical outcome and satisfaction.

### Who can participate?

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.

### What does the study involve?

The study involves the routine assessment of a hip arthroplasty procedure. Patients who participate in the study will be invited for routine visits and during each visit the patient will be asked to complete one questionnaire about their health and one about their activities and their hip. Follow-ups take place at 1, 3, 5, 7 and 10 years after the surgery.

### What are the possible benefits and risks of participating?

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

Where is the study run from?

1. Amphia ziekenhuis Breda, Netherlands
2. Ziekenhuis Netwerk Antwerpen, Merksem, Belgium
3. Orbis Medisch Concern Sittard, Netherlands
4. St. Antoniusziekenhuis, Utrecht, Netherlands
5. Rijnstate ziekenhuis Arnhem/Zevenaar, Netherlands
6. Ikazia ziekenhuis Rotterdam, Netherlands
7. Skånevård Kryh, Hässleholm, Sweden
8. Harrogate District Hospital, Harrogate, UK

When is the study starting and how long is it expected to run for?

February 2012 to June 2025

Who is funding the study?

Stryker European Operations BV (Netherlands)

Who is the main contact?

Sietske Witvoet

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Stefan Bolder

**Contact details**

Location Molengracht Orthopedie

Postbus 90158

Breda

Netherlands

4800

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02520544

## **Secondary identifying numbers**

ATX20120712

# **Study information**

## **Scientific Title**

The ATX registry - accolade stem & Trident/Tritanium cup with X3 insert international multicentre surveillance register

## **Acronym**

ATX

## **Study objectives**

1. Clinical outcome is as good as or better than published results of other press-fit stems
2. Similar clinical results can be obtained with non-designer surgeons as compared to the designer surgeons
3. Tapered stems perform well in all patient populations

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

ETC-AMPHIA Ethics Committee, 20/06/2011, ref: BW/niet WMO nr.080.11

## **Study design**

Prospective international multicentre surveillance register

## **Primary study design**

Observational

## **Secondary study design**

Prospective international multicentre surveillance register

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Osteoarthritis/hip joint

## **Interventions**

No comparative treatments here. This is a follow-up register of one cohort of patients undergoing total hip arthroplasty. Follow-ups are due at 1, 3, 5, 7 and 10 years

## **Intervention Type**

Device

## **Primary outcome measure**

1. To verify the Accolade/Accolade II stem and Trident/Tritanium cup safety during follow-up and survivorship as described by Kaplan-Meier survival curves
2. 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

## **Secondary outcome measures**

1. All intra-operative and post-operative adverse events
2. Standard clinical parameters
3. Harris Hip Score, registered preoperatively and at each follow-up visit
4. Oxford Hip Score, registered preoperatively and at each follow-up visit
5. EQ5D, registered preoperatively and at each follow-up visit

## **Overall study start date**

01/02/2012

## **Completion date**

30/06/2025

# **Eligibility**

## **Key inclusion criteria**

Current inclusion criteria as of 26/08/2014:

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

Previous inclusion criteria:

1. Male and non-pregnant female patients between 18-70 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

## **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

478

**Key exclusion criteria**

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 subjects ability to perform activities of daily living (body mass index, kg/m<sup>2</sup>: BMI ≥ 35)
9. Patients with active or suspected infection
10. Patients with malignancy active malignancy
11. Patients with severe osteoporosis, rheumatoid arthritis (RA), Pagets 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 their ability to assess the performance of the device or the patient has a neurological deficit which interferes with the patients ability to limit weight bearing or place 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)

**Date of first enrolment**

01/02/2012

**Date of final enrolment**

28/02/2015

## **Locations**

### **Countries of recruitment**

Belgium

England

Netherlands

Sweden

United Kingdom

### **Study participating centre**

**Amphia ziekenhuis Breda**

Netherlands

-

### **Study participating centre**

**Ziekenhuis Netwerk Antwerpen**

Merksem

Belgium

-

### **Study participating centre**

**Orbis Medisch Concern Sittard**

Netherlands

-

### **Study participating centre**

**St. Antoniusziekenhuis**

Utrecht

Netherlands

-

### **Study participating centre**

**Rijnstate ziekenhuis Arnhem/Zevenaar**

Netherlands

-

**Study participating centre**  
**Ikazia ziekenhuis Rotterdam**  
Netherlands

-

**Study participating centre**  
**Skåne vård Kryh**  
Hässleholm  
Sweden

-

**Study participating centre**  
**Harrogate District Hospital**  
Harrogate  
United Kingdom  
HG2 7SX

## **Sponsor information**

### **Organisation**

Stryker European Operations BV (Netherlands)

### **Sponsor details**

Herikerbergweg 110  
Amsterdam  
Netherlands  
1101 CM

### **Sponsor type**

Industry

### **Website**

<http://www.stryker.com/>

### **ROR**

<https://ror.org/02nwyam20>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Stryker SA (Switzerland)

## **Results and Publications**

**Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available