Arcos® Revision Stem: Evaluation of Clinical Performance

A Retrospective and Prospective Multi-Center Two-Armed Non-Comparative Clinical Investigation on 200 subjects

PROTOCOL Number (Study ID): GBMET.CR.US19.12
PROTOCOL data and version: March 18, 2015, Version. 6
NCT Number: 01820611

1 STUDY SYNOPSIS

TITLE	Arcos Revision Stem: Evaluation of Clinical Performance
CIP ID	GBMET.CR.US19
SPONSOR	Original: Biomet Administratively transferred: Zimmer GmbH, Zählerweg 4, 6300 Zug, Switzerland
MANUFACTURER	Biomet Orthopedics
STUDY DEVICE (S)	Arcos Modular Revision Femoral System
OBJECTIVE/ENDPOINTS	The primary purpose of this study is to evaluate the clinical performance of the Arcos Revision Stem system, determine the stability of the implants, and evaluate any relationship between bone defect level and the success of the Arcos Stem. Primary Endpoints: - Survivorship and revision rate up to 5 years Secondary Endpoints: - Stability and Fixation of Arcos Hip by radiographic assessment, Relationship between bone defect level, Oxford hip score and Harris hip score postoperative - Adverse events, complications
POPULATION	200 Patients: 100 with BoneMaster HA, 100 without BoneMaster HA Up to ten sites will be used to fulfill enrollment to this study All cases enrolled will be those implanted with either the Cone, Broached, or Calcar Proximal Body and one of the five distal options (Slotted, Bullet-tip, Interlocking, STS, or ETO).
ELIGIBILITY	To be included in the study, a patient have received a revision total hip arthroplasty with the Arcos system. The Arcos system is to be used in accordance to the indications for use and contraindications detailed in the approved labeling of the device.
INCLUSION/EXCLUSION CRITERIA	**<u>Inclusion Criteria</u>** Patients will be included in this study if they received the Arcos Modular Femoral Revision System per the approved indications for use for Arcos specifically. - Patients undergoing Revision of previously failed total hip arthroplasty.

	The Arcos™ Modular Femoral Revision System hip components are single-use implants, intended for uncemented use only. Only subjects who have received the Arcos Revision Stem System will be included in this outcomes study. **<u>Exclusion Criteria</u>** Absolute contraindications include: active infection, sepsis, and osteomyelitis. Relative contraindications include: - Uncooperative patient or patient with neurologic disorders who are incapable of following directions - Osteoporosis - Metabolic disorders which may impair bone formation - Osteomalacia - Distant foci of infections which may spread to the implant site - Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram - Vascular insufficiency, muscular atrophy, or neuromuscular disease. Additionally, all vulnerable subjects (minors, limited or non-readers; adult subjects who cannot consent for themselves; and, pregnant women) will be excluded from participation in this study.
STUDY DESIGN	Retrospective and Prospective Multi-Center Two Armed Non-Comparative Trial
CLINICAL PHASE	Post-Market
NUMBER OF SUBJECTS	200 Patients - 100 with BoneMaster HA - 100 without BoneMaster HA
LENGTH OF STUDY	5 years (24 months enrolment and 5 years follow up)
MATERIAL AND METHODS	Case Report Forms will be completed at 6-12 months, 2-3 years and 5 years post-operatively.

DATA REPORTING

The sponsor will present an annual report to the investigators that will include a summary of the clinical data. The report will contain the results of the Harris Hip at each time point. Also, patient follow-up will be analyzed throughout the data collection according to the following definition and equations:

Lost To Follow-Up: 1. Death

2. Revision

3. Consent Rescinded

Percentage Follow-up = # Patients with Follow-Up_____ x 100

(Theoretically due – Lost To Follow-Up)

Percentage Accounted for = (# with Follow-Up + Lost To Follow-Up) x 100

Theoretically due

At the end of the data collection, a final report will be compiled that will summarize all data collected throughout the data collection, complications throughout the course of the data collection, and general findings.

SAMPLE SIZE JUSTIFICATION

Observational study with 200 Arcos modular femoral revision cases (100 with Bonemaster and 100 without Bonemaster) to assess survivorship and revision rate up to 5 years.

The sample size for this study is based on anticipated sales (1000 during the first year of commercialization) and expected lost-to-follow-up over the first 5 years, with the goal of having a reasonable number of cases for evaluating device survival over the first 5 years of follow up.

An article by Frederick Dorey, et.al. (Journal of Arthroplasty, 1(1):63-69, 1986) recommends having greater than 20 subjects in follow-up when estimating survivorship. Lost to follow-up for this study is estimated to be 10% per year. Thus, if 100 patients of the Arcos with Bonemaster HA and 100 cases of Arcos without Bonemaster are enrolled, there will be 59 patients at 5 years of follow-up for each variant.

Start with 100 cases and assume a loss of 10% per year

o 1 year: 100-10 = 90

- 2 year: 90-9= 81
- 3 year: 81-8=73
- 4 year: 73-7= 66
- 5 year: 66-7 = 59

59 cases is a reasonable number for evaluating survivorship at 5 years per Dorey, et. al.