CLINICAL INVESTIGATION PLAN

CIP ID: BMETEU.CR.EU37

A Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data on the Exceed ABT Acetabular cementless cup system (Implants and Instruments)

NCT number: NCT04255394

Revision 1

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STUDY SPONSOR

Zimmer GmbH

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1 STUDY SYNOPSIS

Title:	A Post-market Clinical Follow-up Study to provide safety, performance and clinical benefits data on the Exceed ABT acetabular cup (implants and instruments) when used in combination with CoC or CoP bearing options.
CIP ID:	BMETEU.CR.EU37
Sponsor:	Zimmer GmbH
Manufacturer:	Biomet UK Ltd
Aim:	To collect survivorship and clinical outcomes long-term data confirming safety, performance and clinical benefits of the Exceed ABT cementless cup when used in combination with ceramic and polyethylene articulating liners.
Objectives:	Primary Objectives: Clinical performance - as measured by clinical score data (HHS, WOMAC and Oxford Hip Score), radiographic assessments and survivorship which will be based on removal of the device. Secondary Objectives: Safety will be evaluated by monitoring incidence of adverse events.
Indication/ Target Population:	<u>Indication:</u> 1. Non- inflammatory degenerative joint disease including oste-oarthritis, avascular necrosis & post – traumatic arthritis. 2. Rheumatoid arthritis 3. Correction of functional deformity 4. Revision of failed joint reconstruction or treatment 5. Treatment of femoral neck and trochanteric fractures of the proximal femur with femoral head involvement and which are unmanageable using other techniques. <u>Population:</u> Male and Female ≥18 years
Inclusion/Exclusion Criteria	<u>Inclusion Criteria:</u> 1. Patients who are capable of understanding the doctor's

	explanations, following his instructions and are able to participate in the follow-up program 2. Patient who gave verbal consent to take part in the study at study commencement and written consent retrospectively at 10 years follow-up by signing the " GDPR Pa-tient Consent Form" 3. Age: => 18 years 4. Male and Female 5. Non- inflammatory degenerative joint disease including osteoarthritis, avascular ne-crosis & post – traumatic arthritis 6. Rheumatoid arthritis, 7. Correction of functional deformity 8. Revision of failed joint reconstruction or treatment 9. Treatment of femoral neck and trochanteric fractures of the proximal femur with femoral head involvement and which are unmanageable using other techniques <u>Exclusion Criteria:</u> 1. Infection, sepsis, and osteomyelitis 2. Patients who are unwilling or unable to give consent, or to comply with the follow-up program. 3. The patient is known to be pregnant or breastfeeding 4. Any vulnerable subjects (= individuals whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate) 5. Uncooperative patient or patient with neurologic disorders who are incapable of following instruction 6. Osteoporosis 7. Metabolic disorder which may impair bone formation 8. Osteomalacia 9. Local and distant foci of infection 10. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram 11. Vascular insufficiency, muscular atrophy, or neuromuscular disease 12. Skeletal immaturity 13. Morbid obesity

	14. Foreign body sensitivity. Where suspected, material sensitivity tests are to be made prior to implantation. 15. Any condition that may interfere with the survival of the implant such as Paget's disease, Charcot's disease, sickle cell anaemia or traits, lower extremity muscular atrophy or neuromuscular disease'
Study Design:	A single-center, cohort observational clinical outcomes study
Clinical Phase:	Post-market
Number of Subjects:	676
Length of Study:	13 years (3 years enrollment plus 10 years follow-up): Post-operative follow-up visits at: 1, 3, 5, 7 and 10 years. Start date: Nov. 2007
Study Device:	Exceed ABT Acetabular System - a multiple bearing option system (implants and instrumentation)
Scores:	Harris Hip Score, Womac Hip Score, Radiographic Assessment & Oxford Hip Score
Documentation:	Paper / Electronic

2 STATISTICAL ANALYSIS PLAN

2.1 Sample Size

This study is a non-comparative case-series, therefore no sample size determination was performed. The aim is to collect clinical outcomes data on the Exceed ABT cementless cup.

2.2 Statistical Analysis

Data collected in the study will be summarized descriptively. Descriptive summaries will be the basis of study reports.

Continuous data (e.g. age) will be summarized through means, medians, standard deviation, minimum, maximum and 95% confidence intervals (CIs) over time periods of interest. Categorical data (e.g. gender) will be summarized using counts, percentages and 95% confidence limits over time periods of interest. Summaries of implant-related revision rates and complication data will be presented as frequencies and percentages. Subgroup summaries will be generated as needed either by strata within the study population (e.g. male vs. female) or by different cut-points (e.g. body mass index (BMI) ranges). Patient confidentiality will be protected at all times, and patient identifiers will not be included in data summaries.