A Multicentre Observational Study to Evaluate Clinical Outcomes of the G7™ Acetabular System

Protocol number: ORTHO.CR.GH20.13
Protocol date: 26 June 2013

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1 STUDY SYNOPSIS

Complete Protocol Title	A Multicentre Observational Study to Evaluate Clinical Outcomes of the G7™ Acetabular System
Protocol Number	ORTHO.CR.GH20.13
Short Protocol Title	G7 Early Evaluator
Sponsor	Zimmer GmbH
Manufacturer	Biomet Inc.; Biomet UK Ltd
Study Device(s)	G7 Acetabular Cup System
Study Objectives/Endpoints	The purpose of this multicenter study is to document the Clinical and Radiographic performance of the cup in both primary and revision procedures at the follow-up time points of 3 months, 1 year, 2 years, and 5 years and to report safety and Survivorship at 7 and 10 years follow-up. Primary endpoint: Harris Hip Score (HHS) at 2 year postoperative Secondary endpoints: a. Oxford Hip Score at 1,2,5 year postop b. Radiographic Evaluation: radiographic outcome, stability, incidence of radiolucencies around the prosthesis and bone remodeling c. Adverse Events/Complications (including revisions/removals of the study hip). d. Survivorship
Indications/Target Population	Subjects who have received G7 with one of three articulations (MOP, COP, COC) in primary or revision procedure and match with the indications for use.
Inclusion/Exclusion Criteria	Inclusion Criteria Selection of subjects for this evaluation should be in accordance with the indications of the G7 cup specifically: Subjects with one of the following indication: - Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis. - Rheumatoid arthritis. - Correction of functional deformity. - Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques. - Revision procedures where other treatment or devices have failed.

	Additional inclusion criteria include: - Male or female. - 18 years of age or older - Subjects willing to return for follow-up evaluations. Subjects who read, understand study information and give written consent (specific local regulatory) Exclusion Criteria Exclusion criteria should be in accordance with Contraindications for the G7 cup. Absolute contraindications include: infection, sepsis and osteomyelitis, Additional contraindications include: - Subjects unable to cooperate with and complete the study - Dementia and inability to understand and follow instructions - Neurological conditions affecting movement - Pregnancy
Study Design	Prospective/Retrospective Observational Multi-Center Non-Controlled post market surveillance study
Clinical Phase	Post-market
Sample Size	A sample size of 101 per group gives 80% power to detect a difference in means for each of the three comparisons.
Length of Study	11 years (1-year enrolment, with a follow-up of 10 years)
Materials and Methods	Case report forms will be completed either in-office or hospital at Pre-op, Intra-Operative, Immediate Post-Operative, and the 3 Months, 1, 2, 5, 7 and 10-year intervals.
Data Collection	Paper/Electronic
Statistical Reporting	Statistical analysis will be conducted by Zimmer Biomet or its designee. Survivorship will be evaluated using Kaplan-Meier.
Scores/Performance Assessments	(modified) Harris Hip Score, Oxford Hip Score, Radiographic Evaluations
Standards	The PMCF is compliant with the below: • ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice. • The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects.

Study Funding	Funding for this clinical study is made available by Zimmer Biomet to support clinical data collection, IRB/EC review fees and other expenses associated with the conduct and execution of this study protocol as outlined in the fully executed Clinical Trial Agreement.