Anatomical Shoulder Inverse/Reverse Post-Market Clinical Follow-Up (PMCF) Study

A multi-centre, non-comparative, prospective post-market surveillance study to obtain clinical and radiographic outcome data on the Anatomical Shoulder Inverse/Reverse System when used in primary shoulder replacement.

Protocol number: 06-U02
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STUDY SPONSOR

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1 STUDY SYNOPSIS

Complete Protocol Title	Anatomical Shoulder™ Inverse/Reverse Post-Market Surveillance Study A Multicenter, non-comparative, prospective post-market surveillance study to obtain clinical and radiographic outcome data on the Anatomical Shoulder™ Inverse/Reverse System when used in primary total shoulder replacement
Protocol Number	06-U02
Short Protocol Title	Anatomical Shoulder™ Inverse/Reverse study
Sponsor	Zimmer GmbH, Sulzer-Allee 8, 8404 Winterthur, Switzerland
Manufacturer	Zimmer Switzerland Manufacturing GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland
Study Device(s)	Anatomical Shoulder™ Inverse/Reverse system
Study Objectives/Endpoints	The objectives of this study is to obtain outcome data on the Anatomical Shoulder™ Inverse/Reverse system by analysis of standard scoring systems and radiographs.
Indications/Target Population	When there is severe distortion of osseous anatomy and loss of normal cuff tendon structure, reconstruction in order to restore function and offer pain relief is possible using the Anatomical Shoulder™ Inverse/Reverse system.
Inclusion/Exclusion Criteria	Inclusion Criteria: • Age - 18 years minimum. • Sex - male and female. • General Health - the patient should be able to undergo surgery and participate in a follow-up program based upon physical examination and medical history. • Informed Consent - patient or patient's legal representative has signed a 'Patient Informed Consent form' • Indications - Diagnosis of disease or trauma in the affected joint, including - Cuff-tear arthropathy - Failure of prior rotator cuff surgery - Irreparable rotator cuff tears associated with loss of glenohumeral stability with the indication for total shoulder arthroplasty.

	- The deltoid muscle has to be intact in all 3 parts (clavicular, acromial as well as spinal). Exclusion Criteria: • Patient is skeletally immature. • Patient is pregnant. • Patient is unwilling or unable to cooperate in a follow-up program. • Patient shows one of the following medical conditions: - Chronic fracture - Acute fracture - Axillary nerve lesion - Severe loss of humeral or glenoid bone - Paralysis of the deltoid muscle - Active Infection - Patient requires one of the following medical interventions: - Implant revision - Glenoid bone grafting - Auto grafts
Study Design	A multicenter, non-comparative, prospective post-marketing study.
Clinical Phase	Post-market
Sample Size	Maximum of 160 study subjects implanted with the study device.
Length of Study	11 years (1 year patient recruitment and 10 year follow-up period). Follow-up evaluations are conducted at 6 weeks and thereafter at 1,2,5 and 10 years post hospital discharge.
Materials and Methods	Case report forms will be completed either in-office or hospital at Pre-op, Surgery, Discharge, and at the 6 week/6months and at 1, 2, 5 and 10 year post-operation intervals.
Data Collection	Paper/Electronic
Statistical Reporting	Data collected will be summarized and reported to each participating investigator. Statistical analysis will be conducted by Zimmer Biomet or its designee. Survivorship will be evaluated using Kaplan-Meier.

Scores/Performance Assessments	Constant-Murley Score, Revisions, Adverse Events, Radiographic Assessment.
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. • European Regulation (EU) 2017/745.
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.

2 STATISTICAL ANALYSIS PLAN

2.1 Statistical Considerations

Data collected in the study will be summarized descriptively. Descriptive summaries will be the basis of study reports to participants, as well as to generate an overall summary of the clinical performance of the various implants captured within the database and may be used for reports and to support presentations and publications as needed.

Summaries will routinely describe categorical data as counts and percentages, and ninety-five percent confidence limits will be generally used to assess differences between different implant configurations. Routine summaries describing continuous data will be in the form of means, medians, standard deviations, minima, and maxima, and ninety-five percent confidence intervals will be used to contrast differences.

Routine summaries of implant survival, return to function, etc. (e.g. time to event) will generally be described via the Kaplan-Meier method and these will generally be accompanied with the corresponding crude rates (expressed as percentages). Routine summaries of complication data will be in the form of frequencies and percentages. Summaries may be further generated for strata within the study population, (e.g. males and females, at different cut-points in the body mass index continuum, etc.).

Patient confidentiality will be protected at all times, and patient identifiers will not be included in study summaries.

2.2 Statistical Analysis

Continuous data (e.g. age, BMI, Constant & Murley Score) will be reported using mean, standard deviation, median, and range. Comparisons between continuous baseline and interim patient visits will be performed using standard statistical tests and will be chosen as appropriate for the scale and distribution of the measures being analyzed. For example, a t-test, Wilcoxon test, or one-way ANOVA (as appropriate) may be performed to assess differences. Comparisons between preoperative and follow-up visit scores will use two-sided comparisons with $\alpha = 0.05$, with no adjustment for multiple comparisons.

Categorical data (e.g. gender) will be reported using frequency and percentage. Comparisons between categorical baseline and interim patient visits will be performed using standard statistical tests and will be chosen as appropriate for the scale and distribution of the measures being analyzed.