Anaverse™ Glenoid System and its instrumentation

Retrospective and Prospective, Non-Controlled Post Market Clinical Follow-Up Study

Protocol number: CME2017-11E
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1 STUDY SYNOPSIS

Complete Protocol Title	Anaverse™ Glenoid System and its instrumentation - Retrospective and Prospective, Non-Controlled Post Market Clinical Follow-Up Study
Protocol Number	CME2017-11E
Short Protocol Title	Anaverse™ Glenoid System and its instrumentation
Sponsor	Zimmer GmbH, Zählerweg 4, 6300 Zug, Switzerland
Manufacturer	Zimmer Switzerland Manufacturing GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland
Study Device(s)	Anaverse™ Glenoid System
Study Objectives/Endpoints	The objectives of this study are to confirm safety, performance and clinical benefits of the Anaverse™ Glenoid System and its instrumentation by analysis of standard scoring systems, radiographs and adverse event records. The safety of the system will be assessed by monitoring the frequency and incidence of adverse events. The performance and clinical benefits will be evaluated by assessment of the overall pain and functional performance, survival, and radiographic parameters of all enrolled study subjects. The primary endpoint is defined by the survival of the implant system at 2 years which is based on removal or intended removal of the Anaverse™ Glenoid System baseplate and will be determined by using the Kaplan Meier method.
Indications/Target Population	Patients suffering from severe shoulder pain and disability indicated for implantation of the Anaverse™ Glenoid System in cases of total shoulder arthroplasty in reversed configuration. Patients who underwent total shoulder arthroplasty conversion from anatomical to reversed will be enrolled for subgroup analysis. Patients must meet all inclusion and none of the exclusion criteria. The *reversed configuration* of the Anaverse Glenoid System is indicated for patients with significant shoulder disability due to gross and irreparable rotator cuff deficiency. A functional deltoid muscle is necessary to use the device. The conversion from anatomical to reversed configuration is indicated for patients that were implanted with the system in the anatomical configuration and that present irreparable rotator cuff and superior migration of the humeral head, leading to a reduction in sub-acromial space.
Inclusion/Exclusion Criteria	Inclusion and exclusion criteria reflect indications and contraindications reported on the device instructions for use (IFU).

	Inclusion criteria:
	• Patient is 18-75 years of age, inclusive.
	• Patient is skeletally mature.
	• Patient is capable of understanding the doctor's explanations, following his instructions and is able to participate in the follow-up program.
	• Patient must have signed EC-approved informed consent.
	• Patient requires a primary reversed total shoulder arthroplasty or a conversion from anatomical to reversed to relieve pain and restore the joint function.
	• Patient has adequate quality and quantity of bone stock to support the prosthesis.
	• Patient meets at least one of the following indications:
	  ○ Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis
	  ○ Conditions consequent to earlier operations
	  ○ Omarthrosis or Osteoarthritis
	  ○ Rheumatoid arthritis
	  ○ Total joint reconstruction following trauma
	• Patient has significant shoulder disability due to gross and irreparable rotator cuff deficiency. A functional deltoid muscle is necessary to use the device.
	• Patient underwent reverse total shoulder reconstruction with the Anaverse Glenoid System before the date of site initiation.
	• Patient has demographic, pre-operative evaluation, operative report and device information available.
	Specific inclusion criteria for Conversion from Anatomical to Reversed Configuration:
	• Surgery was performed with the Anaverse Glenoid System in a previously available anatomical configuration.
	• Irreparable rotator cuff with superior migration of the humeral head, leading to a reduction in sub-acromial space.
	• Superior tilt of the Anaverse Glenoid Baseplate not exceeding 15° compared to scapular axis.
	No evidence of mechanical or fixation failure of the Baseplate, TM Pegs or DPSC Screws, obtained pre- or intra-operatively, which would compromise the success of the conversion surgery.
	
	Exclusion criteria:
	• Patient is unwilling or unable to give consent or to comply with the follow-up program.
	• Patient has any condition which would in the judgment

	of the Investigator place the patient at undue risk or interfere with the study. • Patient is known to be pregnant or breastfeeding. • Patient is a vulnerable subject (prisoner, mentally incompetent or unable to understand what participation to the study entails, a known alcohol or drug abuser, anticipated to be noncompliant). • Patient has any physical conditions that would impair adequate implant support and/or prevent the use of an appropriately sized implant. • Patient has any sign of infection (affecting the shoulder joint or in its proximity). • Patient has glenoid presenting with large defects due to erosion, which would lead to insufficient bony support or malalignment of the devices. • Patient is skeletally immature. • Patient has any sign of neuromuscular compromise (excluding rotator cuff tear). • Patient has vascular deficiency in the affected limb in sufficient degree to endanger the success of the intervention. • Patient has absence of musculo-ligamentous supporting structures. • Patient suffers from joint neuropathy or other conditions that may lead to inadequate skeletal fixation. • Patient has significant injury to the upper brachial plexus. • Patient has non-functional deltoid muscle. Specific exclusion criteria for Conversion from Anatomical to Reversed Configuration: • Unstable fixation of Baseplate after removal of PE Liner. • Superior tilt of Baseplate exceeding 15° compared to scapular axis • Superior malposition of the Baseplate which would prevent correct assembly of the Glenosphere. • Evidence of mechanical or fixation failure of the Baseplate, TM Pegs or DPSC Screws, obtained pre- or intra-operatively, which would compromise the success of the conversion surgery.
Study Design	Retrospective and prospective, non-controlled post market surveillance study.
Clinical Phase	Post-market
Sample Size	30 shoulders.

Length of Study	3 years (1 year of enrollment plus 2 years of follow-up): follow-up visits at 6 weeks, 1 and 2 years postoperatively.
Materials and Methods	Case report forms will be completed either in-office or hospital at Pre-op, Surgery, Discharge, and at the 6 weeks, 1 year, and 2 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. Categorical data, such as incidences and device-related complications, will be summarized using counts and percentages with 95% confidence intervals. Continuous data, such as patient satisfaction scores, will be summarized by using means, medians, standard deviations, minimum, maximums, and 95% confidence intervals. Patient demographics, such as age and gender, will also be similarly summarized and reported on. Patients who underwent reoperations and/or revisions of components other than the baseplate will also be included in the statistical analysis. This subpopulation is not statistically powered; however, it will be included in the statistical analysis. Statistical analyses will be performed using SAS 9.4. The binomial distribution tests will have 80% probability of computing a two-sided 90% confidence interval on survivorship of each device with a non-inferiority margin of 0.09.
Scores/Performance Assessments	Constant-Murley, Patient Satisfaction, 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. .