Post-Market Clinical Follow-Up Study to Provide Safety, Performance and Clinical Benefits Data of the Zimmer® Plates and Screws System applied for Diaphyseal, Proximal Humerus and Proximal Tibia Fractures (Implants and Instrumentation) – A Retro- and Prospective Consecutive Series Study

EMEA

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STUDY SPONSOR

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Study Synopsis

Complete Protocol Title	Post-Market Clinical Follow-Up Study to Provide Safety, Performance and Clinical Benefits Data of the Zimmer® Plates and Screws System applied for Diaphyseal, Proximal Humerus and Proximal Tibia Fractures (Implants and Instrumentation) – A Retro-and Prospective Consecutive Series Study
Protocol Number	MDRG2017-89MS-158T
Short Protocol Title	Zimmer Plates and Screws (ZPS) System Study
Sponsor	Zimmer GmbH, Zug, Switzerland
Manufacturer	Zimmer Inc.
Study Device(s)	ZPS System plates (implants and instrumentation) for which data is being collected within this study*: ○ Diaphysis group: ➢ Compression Plate (2.0 and 2.7):  ➢ Compression Broad Plate:  ➢ Compression Narrow Plate:  ➢ One-Quarter Tubular Plate with Collar:  ➢ Cobra Head Plate:  ➢ Semi-Tubular Plate:  ➢ Straight Plate (1.5 and 2.0mm):

	 ○ Proximal Humerus group: ➢ T-Plate (4.5mm):  ➢ Cloverleaf-Plate:  ○ Proximal Tibia group: ➢ L-Buttress Plate:  ➢ T-Buttress Plate:  ➢ Spoon Plate:  * Plates are grouped per anatomical region they are applied.
Technical Documentation Reference Number	414b, 402a, 401, 850
Study Objectives/Endpoints	The objective of this post-market clinical follow-up (PMCF) study is to collect data confirming safety, performance and clinical benefits of the Zimmer Plates and Screws System (implants and instrumentation) when used to stabilize diaphyseal, proximal humerus and proximal tibia fractures. The primary objective is the assessment of performance by analyzing fracture healing. The secondary objectives are the assessment of safety by recording and analyzing the incidence and frequency of complications and adverse events. Relation of the events to implant, instrumentation and/or procedure should be specified. Subjects' outcomes will also be assessed.

Indications/Target Population	Consecutive series of subjects implanted with plates and screws belonging to the ZPS System according to the indications for use. Please refer to the study device section of this synopsis for more details on the different plates used in this study. Inclusion/exclusion criteria are based on the indications and contraindications in the Instruction for Use (IFU).
Inclusion/Exclusion Criteria	<u>The inclusion criteria are:</u> Patients having received one of the plates belonging to the ZPS System, designed for temporary internal fixation to stabilize fractures during the normal healing process. In this study we will collect data specifically on ZPS plates belonging to the Diaphysis, Proximal Humerus and Proximal Tibia groups. <u>The exclusion criteria are:</u> • Off-label use • Patients under the age of 18 • Prisoners • Severely comminuted fractures in which bone fragments are too small or numerous to adequately fix or maintain a reduced position. • Infection. • Metal sensitivity or intolerance. • Severe osteopenia and/or osteoporosis, or in the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor-like condition of the bone which may compromise fixation. • Sternal or spinal fractures. • Anatomical location in which the device would interfere with nerves, blood vessels, or other vital structures. • Patients with inadequate soft tissue coverage at the implant site.
Study Design	Single-Center, Retro- and prospective, Non-controlled, Non-randomized, Consecutive series of patients
Clinical Phase	Post-market
Sample Size	The goal is to collect data on a total of 112 consecutive cases operated with a plate belonging to one of the three ZPS System groups defined in this synopsis and distributed as following: • 50 consecutive cases treated with a plate of the Diaphysis group.

	• 52 consecutive cases treated with a plate of the Proximal Humerus group. • 10 consecutive cases treated with a plate of the Proximal Tibia group. The cases should be equally distributed between the different plates of each group, if possible.
Length of Study	18 months overall: • Ethics Committee approval • Subject identification, consent and enrollment into the study • Collection of baseline and follow-up (FUP) information available in medical notes from the pre-operative condition to the immediate post-op and last consultation visit • Conduct FUP phone call • Conduct data collection, analyses, write an interim report as well as a final report or a manuscript.
Materials and Methods	Retrospective data will be collected from medical charts including baseline information from the preoperative, operative, immediate post-operative interval and last consultation visit. In addition, a prospective FUP call (min 1 year post-op) will be performed. All data will be entered into an Excel database provided by the Sponsor.
Data Collection	Paper/Electronic
Statistical Reporting	Statistical analysis will be conducted by Zimmer Biomet or its designee. 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 and radiological evaluation of the ZPS System groups described in this protocol. 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 fracture healing rate 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.
Scores/Performance Assessments	Tegner and Lysholm (Proximal Tibia Group), Oxford Shoulder Score (Proximal Humerus Group), EQ-5D-5L (Diaphysis Group); Fracture Healing, Adverse Events

Standards	The PMCF is compliant with the below: • ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice [1]. • The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects [2]. • European Regulation (EU) 2017/745 [3]. • MDCG 2020-10/1 Safety reporting in clinical investigations for medical devices under the Regulation (EU) 2017/74 [4]
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.