Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the DVR® Plating System (Implant and Instrumentation)

A Retrospective Consecutive Series Study

Revision 1

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STUDY SPONSOR

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Title:	Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the DVR® Plating System (Implant and Instrumentation) – A Retrospective Consecutive Series Study
CIP ID:	MDRG2017-89MS-14T
Sponsor:	Zimmer GmbH
Manufacturer:	Biomet Trauma, Warsaw, Indiana, USA
Objectives:	The objective of this retrospective PMCF study is to collect data confirming safety, performance and clinical benefits of the DVR Plating System (implant and instrumentation) when used for the treatment of wrist 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. Patients' outcomes will also be assessed.
Population:	Consecutive series of subjects implanted with one of the DVR Plating System according to the approved/cleared indications. Inclusion/exclusion criteria are in accordance to the indications and contraindications in the IFU. The devices included in the study will be the ones used in accordance with their IFU and/or Zimmer Biomet's approved labeling.
Inclusion/Exclusion Criteria	Inclusion Criteria: All subjects must have been implanted with one of the DVR Plates according to the approved indications.

	Exclusion Criteria: - Off-label use - Cases where there is an active infection - Conditions which tend to retard healing such as, blood supply limitations, previous infections, etc - Insufficient quantity or quality of bone to permit stabilization of the fracture - Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process - Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantations - Cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients - Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized
Study Design:	Single-center, Retrospective, Consecutive series
Clinical Phase:	Post-market
Number of Subjects:	115 cases (in 111 patients) implanted with the DVR Plating System:
Length of Study:	12 months overall: - Ethics Committee approval, patients' identification, consent and enrollment into the study - Collection of baseline information available in medical notes from the pre-OP condition to the immediate post-OP and last consultation visit - Conduct follow-up phone calls, data collection, analysis, and final report

Study Device:	DVR Plates: DVR Crosslock Plates (and respective instrumentation)

Narrow Mini Locked Plate

Extra Narrow Locked Plate

Mini Locked Plate

Narrow Locked Plate

Standard Locked Plate

Wide Locked Plate

Medium Locked Plate

Long Locked Plate

Extra Long Locked Plate

Extra Extra Long Locked Plate

	DVR Wrist Plates (and respective instrumentation) Dorsal Plate  Radial Styloid Plate  Ulna Plate  DVR Volar Rim Plates (and respective instrumentation) DVR Volar Rim  DVR Volar Rim Narrow 
Score:	Patient-Rated Wrist Evaluation Score (PRWE)
Documentation:	Paper / electronic
Statistical Analysis:	Data collected in the study will be summarized descriptively. Continuous data (e.g. age) will be summarized through means, medians, standard deviation, minimum, maximum and 95% confidence intervals (CIs).

	Categorical data (e.g. gender) will be summarized using counts, percentages and 95% confidence limits. Summaries of fracture healing and osteotomy rates, implant related revision rates and complication data will be presented as frequencies and percentages.

References

1. Clinical Investigation of medical devices for human subjects – Good Clinical practice. ISO 14155:2011.