Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the Zimmer® Reconstruction System (Implant and Instrumentation) - A Retrospective Consecutive Series Study

Study Type: Post-market Clinical Follow-up

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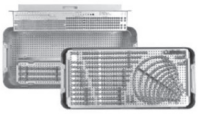

STUDY SPONSOR

Zimmer GmbH
Clinical Affairs
Zählerweg 4
CH-6300 Zug
Switzerland
+41 (0)58 854 80 00

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1 Document History

Protocol Version Number	Date	Description of Changes	Change Author
Rev 0	22-Nov-2019	Creation of Study Document	Nadja Schaetti
Rev 1	02-Dec-2020	Protocol template change from external to internally managed study. Update of deliverables from raw data to report	Nadja Schaetti
Rev 1.1	02-Jul-2021	Updated to new Global CIP template, ISO reference updated to new Standard (ISO 14155:2020), MDCG reference added	Brian Brissoni

2 Contact Information/List of Investigators

Title	Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the Zimmer® Reconstruction System (Implant and Instrumentation) – A Retrospective Consecutive Series Study
Single Identification Number (Clinical Investigational only as per Art. 70 of EU MDR)	N/A
Protocol Number	MDRG-2017-89MS-99T
Study Sponsor Contact Information	Zimmer GmbH Zählerweg 4 CH-6300 Zug Switzerland +41 (0)58 854 80 00
Authorized Representative Contact Information, if applicable (Clinical Investigation only as per Annex XV of EU MDR)	N/A
Monitoring Contact Information	Zimmer GmbH Zählerweg 4 CH-6300 Zug Switzerland +41 (0)58 854 80 00
Name(s) and Address(es) of Principal Investigators(s) and Coordinating Investigator(s), as appointed (Clinical Investigation only as per Annex XV of EU MDR)	A complete listing and details including name, address, contact details and professional position of the Principal and Coordinating Investigators, as appointed, will be maintained the Sponsor's Trial Master File.
Investigational Site Information (Clinical	The study will include 1 site. Details regarding the site involved will be maintained in the Sponsor's Trial Master File.

Investigation as per Annex XV of EU MDR)	
External Organizations, if applicable	N/A

3 Abbreviations

The following abbreviations are used throughout this study protocol:

ADE	Adverse Device Effect
AE	Adverse Event
Case ID	Case Identification Number
CE	Conformité Européene (European Conformity)
CI	Confidence Interval
CRF	Case Report Form
CTA	Clinical Trial Agreement
DD	Device Deficiency
DoH	Declaration of Helsinki
EC	Ethics Committee
EMEA	Europe, Middle East and Africa
FUP	Follow-up
GDPR	General Data Protection Regulation
ICF	Informed Consent Form
ID	Identification
IFU	Indications for Use
ISO	International Standards Organization
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
MEDDEV	Medical Device Directive
OP	Operative
PI	Principal Investigator
PMCF	Post-Market Clinical Follow-Up
PMSP	Post Market Surveillance Plan
Post-OP	Post-operative
PROM	Patient-Reported Outcome Measures
SADE	Serious Adverse Device Effect

SAE	Serious Adverse Event
SS	Study Subject
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

4 Study Synopsis

Complete Protocol Title	Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the Zimmer® Reconstruction System (Implant and Instrumentation) – A Retrospective Consecutive Series Study
Protocol Number	MDRG2017-89MS-99T
Short Protocol Title	Zimmer Reconstruction System
Sponsor	Zimmer GmbH, Zug, Switzerland
Manufacturer	Zimmer Inc.
Study Device(s)	Zimmer Reconstruction System and respective instrumentation  Straight Reconstruction Plate  Curved Reconstruction Plate  Symphyseal B ridge plate  Cortical screw
Technical Documentation Reference Number	401, 402a, 402s, 425b, 850
Study Objectives/Endpoints	The objective of this retrospective post-market clinical follow-up (PMCF) study is to collect data confirming safety, performance and clinical benefits of the Zimmer Reconstruction System (implants and instrumentation) when used for temporary internal fixation and

	stabilization of fractures during the normal healing process. 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 cases implanted with the Zimmer Reconstruction System according to the indications for use. Inclusion/exclusion criteria are in accordance with the indications and contraindications in the Instruction For Use (IFU).
Inclusion/Exclusion Criteria	<u>Inclusion Criteria:</u> Patients having received the Zimmer Reconstruction System for temporary internal fixation and stabilization of fractures during the normal healing process. <u>Exclusion Criteria:</u> • Off-label use • Patients under the age of 18 • 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, Retrospective, Non-controlled, Non-randomized, Consecutive series
Clinical Phase	Post-market
Sample Size	The goal is to collect data on a total of 83 consecutive cases operated with the the Straight Reconstruction Plate, Curved Reconstruction Plate and/or Symphyseal Bridge Plate, aiming for an equal number of each.
Length of Study	12 months overall: • Ethics Committee approval • Identify and enroll subjects 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 data collection and analysis • Write the final report
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. Zimmer Biomet will receive only an anonymized report.
Data Collection	Paper/Electronic
Statistical Reporting	Statistical Analysis will be conducted by the Azienda Ospedaliero Universitaria Senese, Siena, Italy.
Scores/Performance Assessments	Harris Hip Score (HHS), 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, 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.

5 Data Collection Overview

The following information and data will be collected on all cases:

Evaluation	Baseline			Last Consultation Visit (min. 1 year post-op)
	Prior to Surgery	Surgical/Operative	Immediate Post-Operative	
Inclusion/Exclusion Criteria	PI			
Demographic Evaluation	PI			
Physical Exam			PI	
Operative Information/ Surgical Device Information		PI		
Immediate Post-Operative Evaluation			PI	
Harris Hip Score [5].				PI
Fracture Healing (including x-rays and/or clinically)				PI
Protocol Deviation		If required		
Complications/Adverse Events (AE relation or not to device, instrumentation and/or procedure)				

PI: completed by Principal Investigator or qualified designee

6 Introduction and Purpose

Falls and motor vehicle accidents, the two most common mechanisms of traumatic injury [4, 5], sometimes result in fractures or other disruptions of the pelvic ring. Fractures following high-energy trauma are often associated with extensive soft tissue injuries. The state of the surrounding soft tissues and the local blood supply to the bone are the most important factors determining the tendency of the fracture to heal [6-12]. In high-energy pelvic trauma fractures, temporary fixation with plates is indicated to stabilize the pelvic ring in order to control hemorrhage, creates high stability and reduces motion in the joint or at the fracture site.

The Zimmer Reconstruction System is a CE marked and FDA cleared implant system that has been in clinical use since 1995. The purpose of this retrospective PMCF study is to confirm safety, performance and clinical benefits of the Zimmer Reconstruction System when used for temporary internal fixation and stabilization of fractures during the normal healing process.

7 Study Device Information

7.1 Study Device

The Zimmer Reconstruction System is designed to provide temporary fixation of fractures primarily in the pelvic region. The implant system is comprised of straight, curved, and symphyseal bridge reconstruction plates and screws used to fix the plates to the fractured bones. The plates, screws and spherical washers that are manufactured from 316L stainless steel and are provided in a range of sizes and lengths to accommodate patient size and skeletal morphology. Representative illustrations of each implant type, screws and ancillary components appear in Figures 1 (1a through 1e).

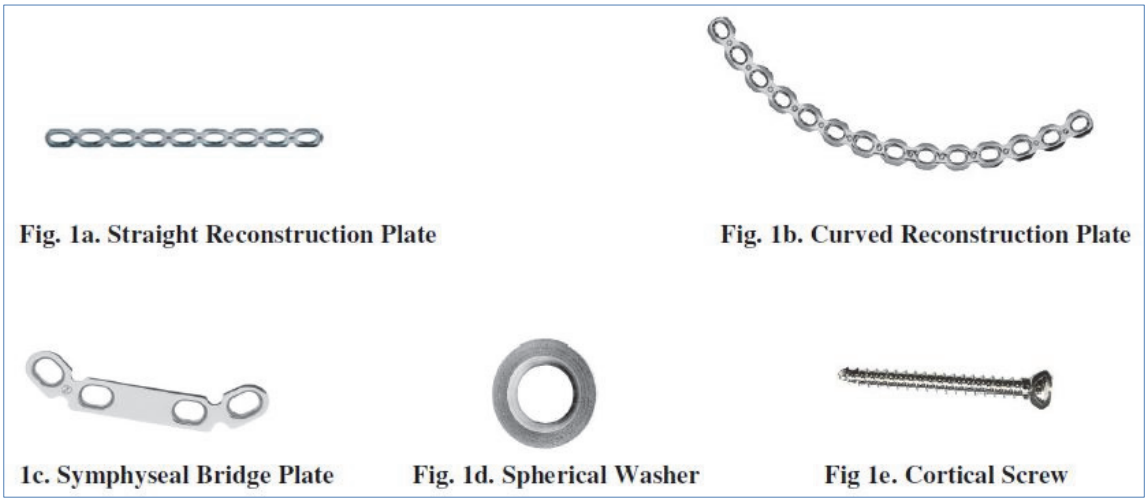

Figure 1: Zimmer Reconstruction System implants, screws and ancillary components

The plates are malleable so they can be precisely contoured to the appropriate shape using plate bending instrumentation as shown in **Figure. 2.**

Figure 2: Bending Pliers Holding a Curved Reconstruction Plate

The plates are available in non-sterile and sterile versions and can accommodate bone screws.

7.2 Device Scope

For simplicity purposes, only the plates and washers are listed in the scope below, however the study aims to collect data on all implants and instruments (incl. ancillary components) of the Zimmer Reconstruction System.

Part Number Sterile	Part Number Unsterile	Item description
00-1179-002-02	47-1179-002-02	ZIMMER RECONSTRUCTION SYSTEM SYMPHYSEAL BRIDGE PLATE 4 HOLES LARGE
00-1179-002-04	47-1179-002-04	ZIMMER RECONSTRUCTION SYSTEM SYMPHYSEAL BRIDGE PLATE 4 HOLES SMALL
00-1179-005-03	47-1179-005-03	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 3 HOLES
00-1179-005-04	47-1179-005-04	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 4 HOLES
00-1179-005-05	47-1179-005-05	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 5 HOLES
00-1179-005-06	47-1179-005-06	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 6 HOLES
00-1179-005-07	47-1179-005-07	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 7 HOLES
00-1179-005-08	47-1179-005-08	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 8 HOLES
00-1179-005-09	47-1179-005-09	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 9 HOLES
00-1179-005-10	47-1179-005-10	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 10 HOLES
00-1179-005-11	47-1179-005-11	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT, 11 HOLES
00-1179-005-12	47-1179-005-12	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 12 HOLES
00-1179-005-13	47-1179-005-13	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT, 13 HOLES

00-1179-005-14	47-1179-005-14	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 14 HOLES
00-1179-005-15	47-1179-005-15	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT, 15 HOLES
00-1179-005-16	47-1179-005-16	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 16 HOLES
00-1179-005-18	47-1179-005-18	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT 18 HOLES
00-1179-005-20	47-1179-005-20	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - STRAIGHT, 20 HOLES
00-1179-005-22	47-1179-005-22	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE- STRAIGHT, 22 HOLES
00-1179-006-06	47-1179-006-06	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 6 HOLES
00-1179-006-08	47-1179-006-08	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 8 HOLES
00-1179-006-10	47-1179-006-10	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 10 HOLES
00-1179-006-12	47-1179-006-12	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 12 HOLES
00-1179-006-14	47-1179-006-14	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 14 HOLES
00-1179-006-16	47-1179-006-16	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 16 HOLES
00-1179-006-18	47-1179-006-18	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED 18 HOLES
00-1179-006-20	47-1179-006-20	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED, 20 HOLES
00-1179-006-22	47-1179-006-22	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED, 22 HOLES
00-1179-006-24	47-1179-006-24	ZIMMER RECONSTRUCTION SYSTEM 3.5 MM RECON BONE PLATE - CURVED, 24 HOLES
00-1179-007-02	47-1179-007-02	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 2 HOLES
00-1179-007-03	47-1179-007-03	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 3 HOLES
00-1179-007-04	47-1179-007-04	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 4 HOLES
00-1179-007-05	47-1179-007-05	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 5 HOLES
00-1179-007-06	47-1179-007-06	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 6 HOLES
00-1179-007-07	47-1179-007-07	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 7 HOLES
00-1179-007-08	47-1179-007-08	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 8 HOLES
00-1179-007-09	47-1179-007-09	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 9 HOLES
00-1179-007-10	47-1179-007-10	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 10 HOLES
00-1179-007-11	47-1179-007-11	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 11 HOLES
00-1179-007-12	47-1179-007-12	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 12 HOLES
00-1179-007-13	47-1179-007-13	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 13 HOLES
00-1179-007-14	47-1179-007-14	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 14 HOLES
00-1179-007-15	47-1179-007-15	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 15 HOLES
00-1179-007-16	47-1179-007-16	ZIMMER RECONSTRUCTION SYSTEM 4.5 MM STRAIGHT RECON PLATE 16 HOLES
00-1179-013-06	47-1179-013-06	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 6 HOLES
00-1179-013-08	47-1179-013-08	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 8 HOLES
00-1179-013-10	47-1179-013-10	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 10 HOLES
00-1179-013-12	47-1179-013-12	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 12 HOLES
00-1179-013-14	47-1179-013-14	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 14 HOLES
00-1179-013-16	47-1179-013-16	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE 16 HOLES
00-1179-013-18	47-1179-013-18	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE, 18 HOLES
00-1179-013-20	47-1179-013-20	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE, 20 HOLES

00-1179-013-22	47-1179-013-22	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE, 22 HOLES
00-1179-013-24	47-1179-013-24	ZIMMER RECONSTRUCTION SYSTEM 2.7 MM STRAIGHT RECON PLATE, 24 HOLES

Table 1. Device Scope of the Zimmer Reconstruction System Implants

7.3 Instrumentation

The instruments are made of stainless steel. Some instruments, such as screwdrivers, have plastic handles. Implant and instrument cases store the plates and associated instrumentation and house them during sterilization.

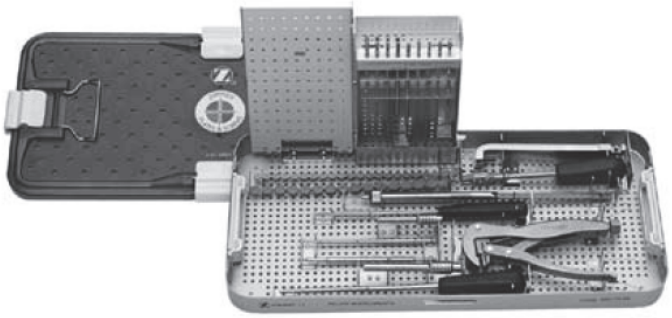

Figure 3: Pelvic Reconstruction Instrument Set

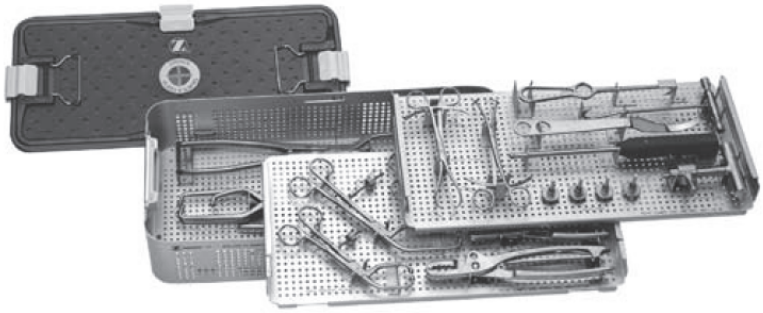

Figure 4: Pelvic Reconstruction Clamp Set

7.4 Ancillary devices

The Spherical washers are used to increase screw head size and fit flush, for fracture fixation optimizing the compression and minimize intrusion of the screw head through the bone during screw insertion (see table 2).

Part number	Item description
00-1179-012-00	ZIMMER RECONSTRUCTION SYSTEM SPHERICAL WASHER FOR USE WITH 3.5 MM SCREW

00-1179-015-00	ZIMMER RECONSTRUCTION SYSTEM SPHERICAL WASHER 2.7 MM I.D.

Table 2. Zimmer Reconstruction System ancillary components

7.5 Compatibility

To determine whether devices have been authorized for use in a proposed combination with Zimmer and/or Biomet products, please contact your sales representative or visit the Zimmer Electronic Labeling Service (eLabeling) website: https://labeling.zimmerbiomet.com/.

7.6 Accountability of devices

Device accountability is not required for this study. The devices used in the study are commercially available via CE 515162.

8 Study Population

The study population will be comprised of a consecutive series of cases implanted with the Zimmer Reconstruction System according to Zimmer Biomet's IFU and meeting the inclusion criteria and none of the exclusion criteria of this study. Inclusion/exclusion criteria are based on the indications and contraindications in the IFU. See below inclusion and exclusion criteria to be considered to determine patient`s eligibility.

8.1 Inclusion Criteria

Patients having received the Zimmer Reconstruction System for temporary internal fixation and stabilization of fractures during the normal healing process.

8.2 Exclusion Criteria

The exclusion criteria are:

- Off-label use
- Patients under the age of 18
- 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.

9 Study Objectives

This is a PMCF study to fulfil the post-market surveillance obligations according to Medical Device Directive, MEDDEV 2.12-2 and the Medical Devices Regulation (MDR 2017/745). The objective of this retrospective PMCF study is to collect data confirming safety, performance and clinical benefits of the Zimmer Reconstruction System (implant and instrumentation) when used for temporary internal fixation and stabilization of fractures during the normal healing process.

- Performance will be evaluated by assessing bone union radiographically and/or clinically
- Safety will be evaluated by monitoring the frequency and incidence of adverse events (AE), serious adverse events (SAE), adverse device effects (ADE), serious adverse device effects (SADE), unanticipated serious adverse device effects (USADE) and device deficiencies (DD). Relation of the events to implant, instrumentation and/or procedure should be specified.
- Clinical benefits will be determined by the Harris Hip Score recorded at the longest follow-up after surgery (at least 1 year post-operative).

10 Study Design and Endpoints

10.1 Disease/Condition Being Treated

In this study the Zimmer Reconstruction system is used to stabilize fractures through temporary internal fixation during the normal healing process.

10.2 Number of Sites and Regions

This is a monocentric study performed at the Hospital Azienda Ospedaliero Universitaria Senese in Siena, Italy.

10.3 Number of Cases and Maximum Enrollment per Investigation Site

The goal is to collect data on a total of 83 consecutive cases operated with the Straight Reconstruction Plates, Curved Reconstruction Plates and/or Symphyseal Bridge Plates defined in the device scope

section of this protocol, aiming for an equal number of each.

10.4 Participating Investigators and Roles (if applicable)

A list of the participating Investigators and their roles can be found in the Appendix B of this document and the Sponsor's Trial Master File.

10.5 Study Design

This is a monocentric, retrospective and consecutive series post-market clinical study. Consecutive series of cases implanted with the Zimmer Reconstruction System between 2010 and 2018 at the Hospital Azienda Ospedaliero Universitaria Senese in Siena, Italy will be identified and included in the study. The consecutive cases will be enrolled in the reverse chronological order that they were operated. This means enrollment will start with patients operated in 2018 and consecutively going backwards towards 2010 until the necessary number of cases has been reached.

10.6 EC Approval

Ethics Committee (EC) approval will be obtained prior to conducting this study. No informed consent, nor data protection regulation notice is needed as Zimmer Biomet will only receive a completely anonymized report and will not have access to any pseudonymized patient data.

10.7 Type and Timing of Observations

This study is designed to be retrospective. To avoid bias, consecutive series of cases will be identified and included in the study. The study duration is expected to be 12 months overall, which corresponds to time dedicated to the retrospective data collection from hospital charts from the pre-operative condition to the last consultation visit (at least 1-year post-operative), to conduct the analysis and to draft the final report.

10.8 Primary and Secondary Endpoint

The aim of this retrospective PMCF study is to collect data confirming safety, performance and clinical benefits of of the Zimmer Reconstruction System and its instrumentation when used for temporary internal fixation and stabilization of fractures during the normal healing process.

10.8.1 Primary Endpoint

The primary endpoint is the radiographical and/or clinical assessment of fracture healing (performance).

10.8.2 Secondary Endpoint

The secondary endpoint is 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.

10.9 Study Hypothesis

10.10 Since this study is an observational study no hypothesis is used in the study. Financing of the Study

Funding for this clinical study is made available by Zimmer Biomet to support clinical data collection, 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 (CTA).

10.11 Definition of Completion of the Study

This study will be completed once an anonymized final report will be provided to and accepted by Zimmer Biomet on a total number of 83 cases treated with the Zimmer Reconstruction System.

11 Study Procedures

11.1 Study Participation

Each consecutive case implanted with the Zimmer Reconstruction System for temporary internal fixation and stabilization of fractures during the normal healing process between 2010 and 2018 at the Hospital Azienda Ospedaliero Universitaria Senese in Siena, Italy will be identified and included in the study until the required sample size of 83 cases is reached.

11.2 Informed Consent

All Subject related data will be kept anonymized. Patient confidentiality will be protected at all times and patients' identifiers will not be included in summaries of the data. The study sponsor will only receive an anonymized final report, therefore no patient consent is needed.

11.3 Information on Data Handling and Processing (GDPR notice)

Due to the retrospective design of this study and the delivery of anonymized data in a final report, no GDPR notice and consent is needed.

11.4 Study Logs

11.4.1 Subject Screening Log

All patients who received the Zimmer Reconstruction System between 2010 and 2018 must be entered into the Subject Screening Log sequentially regardless of their eligibility.

11.4.2 Subject Identification Log

The site shall maintain a log of all subjects included in the clinical investigation, assigning an identification code linked to their names, alternative subject identification or contact information. All patients who meet the inclusion criteria and none of the exclusion criteria must be entered on the log sequentially. If a subject receives multiple implants, a dataset will be recorded per fractured site. Each case, i.e. fractured site, will have a different identification code. A Subject Identification Log must be maintained throughout the study and is included in the Investigator Binder. This list is kept in a safe place in the hospital.

11.5 Determination of Eligibility and Enrollment

Patient eligibility for enrollment will be determined based upon the inclusion/exclusion criteria. Patients must have received the Zimmer Reconstruction System between 2010 and 2018 at the Hospital Azienda Ospedaliero Universitaria Senese in Siena, Italy and meet the inclusion criteria and none of the exclusion criteria in order to be included in the study.

11.6 Pre-operative Assessment

For each case, baseline data will be collected and will include, but will not be limited to the following:

- Inclusion/Exclusion Criteria
- Demographics:
  - Age at operation
  - Gender
  - Weight
  - Height
  - Concomitant diseases
  - Confounders for bone union
- Diagnosis:
  - Fracture cause (e.g. fall from height, motor vehicle accident)
  - Fracture classification (Tile's classification for pelvic ring fractures, AO or Judet classification for acetabulum fractures) (7; 8; 9; 10)
  - Open or closed fracture
  - Existence of additional fractures (i.e. polytrauma)
- Study deviation, if any

11.7 Surgical Techniques

The surgical technique for the Zimmer Reconstruction System is provided in the Regulatory Binder. The use of the study device was according to the IFU and the hospital's standard reconstruction procedures.

11.8 Surgical/Immediate Post-Operative Assessment

Operative and immediate post-operative data will include, but not be limited to the following:

- Op-Date
- Op-Duration (skin-to-skin, min)
- Product/Instrument specifications (e.g. catalogue number, plate type and size, screws used)
- Physical exam: ROM, motility, neurological basic exam
- Radiographic Evaluation
- Length of hospital stay
- Intra-op and immediate post-op complications, adverse events. (Relation of the events to implant, instrumentation and/or procedure should be specified)
- Study deviation, if any

11.9 Follow-up Procedures

Follow-up evaluation was conducted at a minimum of 1 year after surgery. Data collection will include but is not limited to the following:

- FUP date

- Fracture healing (union/non-union) evaluated by x-ray and/or clinically
- Pain and functional performance as reported by the Harris Hip Score (3)
- Adverse events and complications and date of its occurrence (relation to implant, instrumentation and/or procedure should be specified)
- Revisions/Implant removal date and reason (relation to implant, instrumentation and/or procedure should be specified
- Study deviation, if any

11.10 Minimization of Loss to Follow-up

Due to the retrospective design of the study, no follow up visits are planned. Therefore no loss to follow-up is applicable.

11.11 Radiographic Definitions and Methods

- Standard radiographs of the operated bone are captured during the last consultation visit, if available.
- Radiographic parameters include but are not limited to documentation of bone union and any significant radiographic findings.
- All radiographic evaluations performed according to the protocol will be reviewed by the investigator for significant radiographic findings. If a radiographic significant event is identified by the investigator he/she must document the event and report the radiographic findings as needed.

11.12 Recommended Revision Procedure

No revision arm is planned in this study.

11.13 Explant Procedure

In the event a study subject required a revision surgery all explanted components should have been returned to Zimmer Biomet for analysis. Upon removal, the investigator must record his/her findings i.e. damage on the device

In case of an explant procedure each component should be wrapped separately in a compress (or similar material) immersed in 10% formalin and place each component in a separate labeled container to prevent damage during shipping. The implant container(s) should be labelled to identify the catalog number, investigator name, case ID, date of removal, and include a statement indicating the implant is from a clinical study.

Each wrapped implant specimen and any tissue container should be placed into a Bio-hazardous Material bag. Bio-hazard bag should be placed inside a second sealed container.

All explanted devices should be returned to:

Zimmer Biomet

Attention: Product Services Department

1777 W. Center Street

Warsaw, IN 46580

USA

12 Reporting

12.1 Activities Required Prior to Initiation of the Study

12.1.1 Clinical Trial Agreement (CTA) and Financial Arrangements

A fully executed (signed by all required parties) CTA must be on file with the Sponsor prior to any investigator participating in this study. This agreement must explain the financial arrangement with the investigative site.

12.1.2 Ethics Committee Protocol Approval

This study protocol must be submitted to and approved by the Investigator's EC. A copy of the EC approval letter must be submitted to the Sponsor. The letter should identify the following:

- Protocol name and/or number.
- Date of EC meeting (if available).
- Date of approval.
- Date of expiration.
- Signature of EC.

12.1.3 Clinicaltrials.gov Registration

The Sponsor will be responsible for registering this study on www.ClinicalTrials.gov if required by local and national regulations.

12.2 Clinical Data Collection/Submission

12.2.1 Summary of Data Collection

Study data will be summarized in an anonymized final report. A final report template will be provided by the Sponsor. Study data will be collected from patients charts and transferred into a study-specific Excel database. The database will not be shared with the Sponsor. If a subject receives multiple implants, a dataset will be recorded per fractured site.

The following completion guidelines should be followed:

- Complete carefully and accurately.
- Be sure that data on the source documents match that which is entered in the database.
- Ensure that all fields are completed. The investigator must retain the subject data sources in accordance with local law and regulations.
- The investigator should take measures to prevent accidental or early destruction of the study related materials.

- Ensure that data in the final report is aligned with the source data.

The following information and data will be collected on all cases and summarized in the final report:

- **Preoperative Information**: Inclusion/Exclusion criteria, demographic data, and diagnosis.
- **Operative and Immediate Postoperative Information:** Date of surgery, duration of surgery, operated side, surgical device information (devices, ancillary devices, instrumentation), length of hospital stay, complications and adverse events.
- **Last Consultation Visit (at least 1 year post-op):** Date of visit, radiographic assessment of fracture healing (if available), clinical assessment of fracture healing, complications and adverse events and Harris Hip Score.
- **Adverse Events:** Complications, reoperations, revisions
- **Protocol Deviation**, if applicable

12.2.2 Data Submission

The final report will be sent to Zimmer Biomet. The completed database will remain at the hospital and will not be shared with Zimmer Biomet. Copies of the original x-rays taken at the site during the indicated evaluations should be made available to the Sponsor upon request. The original paper source documents, if any, must be kept in a secure location during the course of the study and maintained in accordance with regional and/or national laws/regulations, and EC requirements.

Each party will notify the other party without undue delay upon becoming aware of any Personal Data Breach affecting Patient and /or User Personal Data. The parties will cooperate fully with each other and use commercially reasonable endeavors to assist each other in relation to any reporting or notification obligations in the event of a Personal Data Breach affecting Patient and/or User Personal Data. Further details for handling potential data breach can be found in the respective section in the CTA.

12.2.3 Quality Assurance of Data

The Investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the final report. Data summarized in the final report should be consistent with the source documents or the discrepancies should be explained.

12.2.4 Patient Privacy and Identification

All patient related data will be kept anonymized and Zimmer Biomet will only receive an anonymized final report..

12.2.5 Data Management

The Investigator and his team is responsible for the data management since the Sponsor only receives an anonymized final report.

12.3 Reporting Requirements

12.3.1 Investigator Reporting Responsibilities

The Investigator should ensure the accuracy, completeness, legibility, and timeliness of data reported to the Sponsor in accordance with this protocol. The Investigator or Designee will provide periodic reports to their EC as required to maintain EC approval throughout the study and will provide any required final reporting to the EC upon study completion/termination. A copy of all EC (re-)approval letters must be submitted to the Sponsor. If the EC terminates or suspends its approval of the study, the Investigator or Designee will suspend study-related activities and will promptly notify the Sponsor. The Investigator should also promptly provide written reports to the Sponsor and the EC regarding any changes significantly affecting the conduct of the study, and/or increasing risk to the subjects.

12.3.2 Retention of Records

Study records must be retained by the Investigator or Designee for a minimum of 15 years from the Investigator's study termination date, or per applicable regulatory and/or EC requirements (whichever time period is greater and allowed by local regulation). Measures shall be taken to prevent accidental or premature destruction.

Study records are defined as all information in original records, certified copies of original records of clinical findings, observations or other activities in a clinical study, including source data initially recorded in an electronic format, necessary for the reconstruction and evaluation of the clinical study. This may include but is not limited to: hospital records, clinic records, laboratory notes, device accountability records, photographs, radiographs, subject casebooks, regulatory records, and all other study-related documents

12.4 Management of Intercurrent Events

12.4.1 Failure to Obtain Informed Consent and/or GDPR notice

Due to the retrospective design of this study, Informed Consent and GDPR consent s not required.

12.4.2 Revision

In the event that removal of one or more of the study related components was necessary, the Investigator has determined the best treatment and/or revision method for the subject. All revision surgeries should be reported as Adverse Events in the

final report.

12.4.3 Investigator Withdrawal

Due to the retrospective design of this study, investigator withdrawal is not applicable for this study.

12.4.4 Subject Withdrawal

Due to the retrospective design of this study, subject withdrawal is not applicable for this study.

12.4.5 Lost to Follow-up

Due to the retrospective design of this study, lost to follow-up are not applicable.

12.4.6 Protocol Deviations

The Investigator should not deviate from the agreed upon protocol unless it is to eliminate hazard to the patient. However, any deviation from the protocol has to be documented along with an explanation for the deviation and reported to the Sponsor. Each significant deviation will be reported to the Ethics Committee, if applicable, within the appropriate deadlines stipulated by the appropriate regulatory authorities. Significant deviations are defined as those impacting or potentially impacting patient safety. The Sponsor shall take appropriate corrective and preventative actions to protect the safety of subjects, users, and other persons. Investigator disqualification criteria leading to exclusion from the clinical study include fraud, misconduct and serial non-compliance.

12.4.7 Study Termination

The study terminates after Zimmer Biomet has received and approved the final report. If the Sponsor decides to terminate the study early, the Sponsor will inform the Investigator of the reason for early study termination. It is the responsibility of the Investigator to inform their EC as applicable according to local and national laws/regulations.

12.4.8 Adverse Events

See Safety Management – Medical Events/Adverse Events Section of this protocol for additional information regarding adverse event classifications.

Reporting and Documentation of Adverse Events and Adverse Device Effects

Adverse Events and Adverse Device Effects have to be documented ideally including information on the type of event, date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device, instrumentation and/or procedure. Further, the outcome of complications has to be documented and summarized in the final report. In case of early termination of the study, further follow-up of the patient shall proceed according to the hospital's standard procedure.

Reporting and Documentation of Serious Adverse Events, Serious Adverse Device Effects, and Device Deficiencies

Serious Adverse Events and **Serious Adverse Device Effects** have to be **reported to the Sponsor as soon as possible**. The incidence has to be documented over the whole time of the investigation ideally including information on the type of event, date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device, instrumentation and/or procedure based on the evaluation of the investigator. The outcome of such complications has to be documented and summarized in the final report. In case of early termination of the study, further follow-up of the study subject shall proceed according to the hospital's standard procedure.

Device Deficiencies that did not lead to an adverse event but **could have led** to a medical occurrence if suitable actions had not been taken, if intervention had not been made or if circumstances had been less fortunate shall be **reported to the Sponsor as soon as possible**, as well.

The **Investigator** is responsible for reporting all SAEs, SADEs, USADEs and Device Deficiencies that could have led to a SADE to the Ethics Committee if required by national regulations or by the EC.

13 Safety Management – Medical Events/Adverse Events

Adverse events are required to be summarized in the final report.. The Investigator or Designee will also promptly provide the Sponsor with any additional requested information required for the Sponsor to comply with regulatory requirements. If applicable per their reporting requirements, the Investigator or Designee will also report applicable adverse event(s) to their EC.

The following definitions are from ISO 14155:2020 [1].

13.1 Classification of the Event

13.1.1 Adverse Event (AE)

Untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated.

Note 1: This definition includes events related to the investigational medical device or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.

13.1.2 Serious Adverse Event (SAE)

A Serious Adverse Event is an adverse event that led to any of the following:

a. death,

b. serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:

   1. a life-threatening illness or injury, or
   2. a permanent impairment of a body structure or a body function including chronic diseases, or
   3. in-patient or prolonged hospitalization, or
   4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.

c. fetal distress, fetal death, a congenital abnormality or birth defect including physical or mental impairment.

Note: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event.

13.1.3 Serious Health Threat

Signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health of subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons.

Note 1: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibly of multiple deaths occurring at short intervals.

13.1.4 Adverse Device Effect (ADE)

An Adverse Device Effect is an adverse event related to the use of an investigational medical device.

Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment implantation, installation, or operation, or any malfunction of the medical device.

Note 2: This definition includes any event resulting from use error or from intentional misuse of the medical device.

Note 3: This includes 'comparator' if the comparator is a medical device.

13.1.5 Serious Adverse Device Effect (SADE)

A Serious Adverse Device Effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

13.1.6 Unanticipated Serious Adverse Device Effect (USADE)

An unanticipated adverse device effect is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment.

Note 1: Anticipated serious adverse device effect (ASADE) is an effect which by nature, incidence, severity or outcome has been identified in the risk assessment.

13.1.7 Device Deficiency (DD)

A Device Deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance.

Note 1: Device Deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

Note 2: This definition includes device deficiencies related to the investigational medical device or comparator.

It is important to document in the study also all device deficiencies that could have led to a medical occurrence but did not lead to an adverse event.

13.2 Causality Assessment (Relation to Device)

The relationship between the use of the medical device (including the medical - surgical procedure) and the occurrence of each adverse event shall be assessed and categorized. During causality assessment activity, clinical judgement shall be used and the relevant documents, such as the Investigator's Brochure, the Clinical Investigation Plan or the Risk Analysis Report shall be consulted, as all the foreseeable serious adverse events and the potential risks are listed and assessed there. The presence of confounding factors, such as concomitant medication/treatment, the natural history of the underlying disease, other concurrent illness or risk factors shall also be considered.

Each adverse event will be classified according to four different levels of causality:

- Not Related
- Possible (Uncertain)
- Probable
- Causal Relationship (Definitely related)

The Sponsor and the investigators will use the following definitions to assess the relationship of the adverse event to the investigational device, the comparator or the investigation procedure.

13.2.1 Not Related

Relationship to the device, comparator or procedures can be excluded when the event has no temporal relationship with the use of the investigational device, or the procedures related to application of the investigational device.

13.2.2 Possible (Uncertain)

The relationship with the use of the investigational device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.

13.2.3 Probable

The relationship with the use of the investigational device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.

13.2.4 Causal Relationship (Definitely related)

The serious adverse event is associated with the investigational device, comparator or with procedures beyond reasonable doubt.

Note: Complications caused by concomitant treatments not imposed by the clinical investigation plan are considered not related. Similarly, several routine diagnostic or patient management procedures are applied to patients regardless of the clinical investigation plan. If routine procedures are not imposed by the clinical investigation plan, complications caused by them are also considered not related.

13.3 Review of Reported Events

The Sponsor will review the investigator's assessment of all reported events submitted to determine and document in writing their seriousness and relationship to the study device and related procedures required by this protocol. In case of disagreement, the sponsor will consult the investigator for clarification and correction if required. If the disagreement cannot be resolved, the Sponsor shall communicate both opinions to the Post Market Surveillance team for further investigation and required reporting if applicable.

13.4 Intensity of Symptoms

13.4.1 Mild

The subject is aware of the sign or symptom, but finds it easily tolerated. The event is of little concern to the subject and/or little clinical significance. The event is not expected to have any effect on the subject's overall health or well-being.

13.4.2 Moderate

The subject has discomfort enough to cause interference with or a change in usual activities. The event is of some concern to the subject's health or well-being and may require medical intervention and/or close follow-up.

13.4.3 Severe

The event interferes considerable with the subject's usual activities. The event is of definite concern to the subject and/or poses substantial risk to the subject's health or well-being. The event is likely to require medical intervention and/or close follow-up and may be incapacitating or life threatening. Hospitalization and treatment may be required.

Note: The term "severe" refers to the intensity of the event and can be used with any event, without regard to whether or not it meets the criteria for being classified as "serious" or "unanticipated". For example, a subject can have a severe headache, but it is not a serious event.

13.5 Outcome Definitions

The outcome is reported in relationship to the Adverse Event, not the treatment rendered for the event (if any).

13.5.1 Resolved

This outcome indicates the event has improved or recuperated.

13.5.2 Resolved with Sequelae

This outcome indicates the subject recuperated but retained pathological conditions resulting from the prior disease or injury.

13.5.3 Resolving*

This outcome indicates that the event is improving.

13.5.4 Not Resolved*

This outcome indicates that the adverse event has not improved or recuperated.

13.5.5 Fatal*

The adverse event resulted in the termination of life.

13.5.6 Unknown*

The outcome of the adverse event is not known, not observed, not recorded, or patient refused to provide information to make an outcome determination.

*Per Regulation (EU) 2017/745 [3], all serious adverse events will be classified according to event status outlined in MDCG 2020-10/1 [4] when used to support MDR reporting requirements. These event statuses include Resolved, Resolved with Sequelae, Death,

and On-going. In order to comply with this reporting requirement, all serious adverse events or Device Deficiency (DD) with outcomes classified as ‘Resolving’, ‘Not Resolved’, or ‘Unknown’, will be reclassified as ‘On-going’ and all serious adverse events classified as 'Fatal' will be reclassified as 'Death'.

14 Monitoring

Prior to initiating the clinical study, the Sponsor may conduct a site evaluation visit to ensure the Investigator and study staff understands the study protocol and requirements and have adequate time and resources to implement and conduct the study. Prior to study initiation,EC approval and a fully executed CTA must be in place.

This is a post-market study that does not involve investigational products or procedures, and there is no physical risks to the patients to be included in the study. Many assessments, such as the Harris Hip Score were used as standard-of-care for this patient population and do not require special training for their use in the study. As such, site initiation visits may be conducted remotely for this study.

During the course of the study, the Sponsor would conduct periodic central monitoring if necessary and maintain contact with the study staff to monitor compliance and evidence of adverse events, in accordance with the Sponsor’s policies and procedures. The Sponsor will address any identified non-compliance with the executed CTA, study protocol, and applicable regulatory requirements.

If onsite monitoring visit(s) are deemed appropriate by the Sponsor, the Investigator will permit representatives of the Sponsor’s monitoring team to have direct access to inspect all source data/documents, study documents/binders, study subject forms, database, corresponding sections of study subject medical/hospital records, and any other documents relevant to the study.

Additional details are provided in the Monitoring plan.

15 Risk Analysis

A discussion of the different types of risks and benefits involved with participation in the investigation, including, but not limited to:

15.1 General

Since all patients have already been operated with the study device and data is only collected retrospectively, there are no anticipated risks specific to study participation. There are no experimental procedures in this study, and participation in this study is not anticipated to affect the medical treatment of included subjects.

When used in accordance with product labelling, the risks associated with the use of the Zimmer Reconstruction System are similar to those of standard, stainless steel systems used for the same

clinical indication or purpose. These risks are either surgical risks or risks associated with the subject procedure/study device. Unanticipated adverse events can also occur.

A list of adverse events (AE) and anticipated adverse device effects (ADE) can be found in the Instruction for Use of the system (see “Adverse Effects” section). Investigators should refer to it.

15.2 Indemnification

The indemnification provision is located in the Indemnification section of the executed CTA.

If an injury is caused to a patient as a result of procedures undertaken in accordance with the Study, the Sponsor is liable for damages resulting from the Study. Zimmer GmbH maintains product liability and excess liability insurance coverage through its parent company Zimmer Holdings, Inc.

16 Statistical Methods

16.1 Sample Size Calculation

The overall success rate of the Zimmer Reconstruction System will be calculated based on the percentage of subjects who have successful fracture healing. The following hypothesis will be tested by exact binomial test

$$H0: E1 - E0 \leq -\delta E$$
$$Ha: E1 - E0 > -\delta E$$

Where:
E0 = 90%, the expected success rate of similar devices to the Zimmer Reconstruction System [13]
E1 = the success rate in the Zimmer Reconstruction System treatment group
δE = 0.10, non-inferiority margin for fracture healing

In addition, one-sided 95% exact confidence Interval (CI), lower limit of the success rate, will be calculated.

The sample size was estimated based on the expected performance of 90% fracture union rate. The sample size includes a 10% non-inferiority margin (90% - 10% = 80%). The expected Clinical Performance Rate of the Zimmer Reconstruction System is assumed as 90%.

Based on the hypothesis test above, a sample size of n = 83 will provide approximately 80% power for the one-sided exact binomial test at 0.05 significant level. The sample size was calculated using SAS for Windows version 9.4. The aim of this study is to include a total number of 83 cases treated between 2010 and 2018 with implants of the Zimmer Reconstruction System at the Azienda Ospedaliero Universitaria Senese in Siena, Italy.

16.2 General Statistical Methods

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 Zimmer Reconstruction System 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).

17 Quality Control & Quality Assurance

The study is conducted in accordance with the ISO 14155:2020 [1] and the Declaration of Helsinki [2].

The Investigator will be required to permit representative(s) of the Sponsor's monitoring team to inspect the database and corresponding sections of the study patients' office records and/or hospital original medical records. These audits will be done for quality assurance purposes, i.e. verifying adherence to the Clinical Investigation Plan and the completeness and accuracy of the data being entered on the database.

The Clinical Investigation Plan will be provided to the participating study center. The Investigators will be fully trained in the proper reporting and submission of trial data prior to patient enrolment. The completion of the database, database data quality, and data queries management for missing or unclear data performed before the statistical evaluation is responsibility of the investigator, since the sponsor will have access only to anonymized final data.

There are regular meetings between the Investigators and Zimmer Biomet Clinical Affairs staff. Written correspondence to the site is used to inform the Investigators of routine study details and to update them on study status.

18 Suspension or Premature Termination of the Clinical Investigation

Zimmer Biomet may decide to suspend or prematurely terminate the clinical study at the investigational site if, for example, information becomes available that the data indicates that the results significantly differ from the study objectives or statistical endpoints.

In the case of an early termination of the study, the EC and regulatory authority(ies) should be informed in accordance with regional and/or national laws/regulations, and EC requirements. The reasons for termination should be provided and documented.

In case the study got suspended or prematurely terminated before a subject has been

included in the study, the study subject shall proceed according to the investigator's standard of care or hospital's standard procedures.

19 Vulnerable Populations (as applicable)

Patients that are within one or more vulnerable populations, including children and prisoners are to be excluded from this study. Due to the retrospective design of the study and the reporting of only anonymized data there is no need of a informed consent process, as decided by the EC.

20 Amendments / Modifications to the Clinical Investigation Plan

The use of waivers from the clinical protocol is prohibited. All amendments to this clinical protocol shall be agreed to by the Sponsor and be recorded with a justification for the amendment prior to implementation. Approval from the EC must be obtained prior to implementation of the amended protocol, if required by regional and/or national laws/regulations. In the case of an amendment to the protocol, the revision history will be documented in the Document History section of this protocol.

21 Publication Policy

Both the Principal Investigator and the Sponsor have the right to publish or allow the results of the clinical study to be published. The Principal Investigator recognizes that the Sponsor has a special interest in the results of the clinical study and will submit manuscripts or final reports to the Sponsor prior to publication. If the Sponsor desires changes to be made, these are communicated to the Principal Investigator within 30 days of submission. Pooled data may be used for training and meetings.

22 Signatures

Herewith, the undersigned certify that they have read and examined the present protocol carefully and declare that they are in agreement with the demands and conditions noted. They hereby consent that they will perform the study according to the requirements of the Declaration of Helsinki and the ISO 14155:2020, as well as according to any regional or national regulations, as appropriate.

Study Manager (Name and job title/ Date/ Signature)

Brian Brissoni, Clinical Research Associate		

Head of Clinical Affairs or designee (Name and job title/ Date/ Signature)

Hassan Achakri, Clinical Operations Director		

23 References

1. *Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice.* s.l. : ISO 14144:2020, 2011.

2. *WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI, Ethical Principles for Medical Research Involving Human Subjects.* Seoul : 59th WMA General Assembly, October 2008.

3. *REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*

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9. *Pelvic ring injuries: classification and treatment.* Gray, A., Chandler, H., Sabri, O. 2, s.l. : Orthopaedics and Trauma, 2018, Bd. 32. p. 80-90.

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12. *Fractures of the Acetabulum: Classification and Surgical Approaches for Open Reduction.* Judet, R., Judet, J., Letournel, E. 8, s.l. : The Journal of Bone and Joint Surgery, 1964, Bde. 46-A. p. 1615-1646.

13. Zimmer Reconstruction System PMSP_WAR_TM_008 Rev 1

24 Appendices

A. Study Logs
B. List of Investigators
C. List of all applicable Instruments
D. Investigator's Consent to the Clinical Investigation Plan