Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the ToggleLoc™ 2.9mm Soft Tissue System (Implants and Instrumentation) in the Elbow

A Multicenter Retrospective Consecutive Study

MDRG2017-89MS-72SM

V 1.2

20.SEP.2022

GLOBAL

NCT05519228

STUDY SPONSORS

Zimmer GmbH
Zählerweg 4
6300 Zug, Switzerland
+41 (0)58 854 80 00

Zimmer Biomet
Clinical Affairs Department
1800 West Center Street
Warsaw, IN 46580
800-613-6131

Complete Protocol Title	Post-market Clinical Follow-up Study to Provide Safety, Performance and Clinical Benefits Data of the ToggleLoc™ 2.9mm Soft Tissue System (Implants and Instrumentation) in the Elbow - A Multicenter Retrospective Consecutive Study
Protocol Number	MDRG2017-89MS-72SM
Short Protocol Title	ToggleLoc 2.9 Elbow Study
Sponsor	Zimmer Biomet
Manufacturer	Biomet Sports Medicine
Study Device(s)	ToggleLoc 2.9mm Soft Tissue System (Implants and Instrumentation)
Technical Documentation Reference Number	EU7010.IIb
Study Objectives/Endpoints	The objective of this post-market clinical follow-up study is to collect data confirming safety, performance and clinical benefits of the ToggleLoc 2.9mm Soft Tissue System when used for soft tissue to bone fixation in the elbow. The primary objective is the assessment of performance by analyzing soft tissue to bone healing in the elbow. The secondary objective is the assessment of safety and clinical benefits. Safety will be evaluated by recording and analyzing the incidence and frequency of complications and adverse events. Relation of the events to device, instrumentation and/or procedure will be specified. Clinical benefits will be assessed by recording patient-reported outcome measures (PROMs) at the longest follow-up after surgery (minimum one year).
Indications/Target Population	Consecutive series of patients who have been operated with the ToggleLoc 2.9mm Soft Tissue System in the elbow and who meet the inclusion criteria and none of the exclusion criteria. Inclusion/exclusion criteria are based on the indications and contraindications in the Instruction for Use (IFU).
Inclusion/Exclusion Criteria	Inclusion Criteria - Patients who received the ToggleLoc 2.9 mm Soft Tissue device for soft tissue to bone fixation in the elbow. - Patients 18 years or older and skeletally mature.

	- Patients capable of understanding the surgeon's explanations and following his/her instructions, able and willing to participate in the follow-up program and who gave consent to take part in the study. Exclusion Criteria - Infection. - Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue. - Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. - Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device. - Patients who have any condition that would in the judgment of the Investigator place the patient at undue risk or interfere with the study. - 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 non-compliant). - Off-label use.
Study Design	Global, Multicenter, Retrospective, Consecutive series
Clinical Phase	Post-market
Sample Size	83 cases implanted with the study device in the elbow.
Length of Study	18 months
Materials and Methods	Clinical records of these patients will be obtained from the clinic database, including pre-operative and intraoperative information. A final follow-up (FUP) visit (minimum 1-year post-operation) will be conducted by phone or on site. Protocol deviations and adverse events will be captured throughout the study.
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.

	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 evaluation of the ToggleLoc 2.9mm Soft Tissue System and its instrumentation when used in the elbow. 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 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, preop diagnosis) or by different cut-points (e.g. body mass index (BMI) ranges). Patient confidentiality will be protected at all times, and patient identifiers will not be included in data summaries.
Scores/Performance Assessments	EuroQol (EQ-5D), Oxford Elbow Score, 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.