Post-market Clinical Follow-up Study to Collect Safety, Performance and Clinical Data of the EZ Pass Suture Passer (Instrumentation) and Precision Flexible Reamers (Instrumentation)

A Retrospective Consecutive Series Study

MDR- EZ Pass Suture Passer and Precision Flexible Reamers

MDRG2017-89MS-32SM

Version 4.1

27 Apr 2021

Region: Americas

STUDY SPONSOR

Zimmer Biomet
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I. Contact Information/List of Investigators

Title	Post-market Clinical Follow-up Study to Collect Safety, Performance and Clinical Data of the EZ Pass Suture Passer (Instrumentation) and Precision Flexible Reamers (Instrumentation)
Protocol Number	MDRG2017-89MS-32SM
Study Sponsor Contact Information	Zimmer Biomet, Clinical Affairs Dept. 1800 W. Center St, Warsaw, IN 46580 Phone: (800) 613-6131, Fax: (574) 372-4710
Monitoring Contact Information	Zimmer Biomet, Clinical Affairs Dept. 1800 W. Center St, Warsaw, IN 46580 Phone: (800) 613-6131, Fax: (574) 372-4710
Investigational Site Information (Clinical Investigation as per Annex XV of EU MDR)	The study will include a single site. Details regarding the site involved will be maintained in the Sponsor's Trial Master File.
External Organizations, if applicable	N/A

II. Abbreviations

ADE- Adverse Device Effect

AE- Adverse Event

ASADE- Anticipated Serious Adverse Device Effect

CE- Conformité Européene

CFR- Code of Federal Regulations

CRF- Case Report Form

CTA- Clinical Trials Agreement

DD- Device Deficiency

DoH- Declaration of Helsinki

EC – Ethics Committee

EDC- Electronic Data Capture

EPR- Expected Performance Rate

EU- European Union

FDA- Food and Drug Administration

HIPAA- Health Information Portability and Accountability Act

ICF- Informed Consent Form

IFU- Instructions For Use

IRB- Institutional Review Board

ISO- International Organization for Standardization

MDR- Medical Device Regulation

PHI- Protected Health Information

PMCF- Post Market Clinical Follow-Up

SADE- Serious Adverse Device Effect

SAE- Serious Adverse Event

USADE- Unanticipated Serious Adverse Device Effect

III. Study Synopsis

Title	Post-market Clinical Follow-up Study to Collect Safety, Performance and Clinical Data of the EZ Pass Suture Passer (Instrumentation) and Precision Flexible Reamers (Instrumentation)
Protocol Number	MDRG2017-89MS-32SM
Sponsor	Zimmer Biomet 1800 W. Center St, Warsaw, IN 46580, United States
Manufacturer	Biomet Sports Medicine 56 East Bell Drive, PO Box 587, Warsaw, IN 46581 USA
Study Device(s)	EZ Pass Suture Passers (Instrumentation) and Precision Flexible Reamer (Instrumentation) See appendix for specific SKUs and descriptions
Study Objectives/Endpoints	The objective of this study is to confirm the safety and performance of the EZPass Suture Passer Instrumentation and the Precision Flexible Reamer Instrumentation. Ultimately, clinical performance will be assessed retrospectively through survey questions that evaluate the safety and performance of these instruments. The primary objective of the study is to confirm the safety and clinical performance of the EZPass Suture Passer and the Precision Flexible Reamer Instrumentation.
Indications/Target population	All subjects were operated on with either the EZPass Suture Passer or the Precision Flexible Reamer Instrumentation will be considered for enrollment. Inclusion Exclusion criteria are based on the indications and contraindications in the Instructions for Use (IFU). The instruments included in the study were used in accordance with their IFU and Zimmer Biomet's approved labeling.
Inclusion/Exclusion criteria	Inclusion Criteria: • EZ Pass Suture Passer: Intended as an open or arthroscopic instrument utilized in conjunction with a nitinol wire or nylon monofilament to aid in passing suture through soft tissue. • Precision Flexible Reamer: This device is a hand held, or hand-manipulated device, intended to be used in ACL and PCL reconstruction surgeries and is intended for medical purposes to manipulate tissue, or for use with other devices in these surgeries. • Patient must be 18 years of age or older.

	Exclusion Criteria: • Any use other than the approved uses indicated in the Instructions for Use (IFU).
Study Design	Retrospective, Single-Center, Non-Randomized, Non-Controlled, Single Cohort Study, Survey
Clinical Phase	Post-Market Clinical Follow-Up (PMCF)
Sample Size	A minimum of 51 enrolled subjects were operated on with the EZ Pass Suture Passer Instrumentation and a minimum of 51 enrolled subjects were operated on with the Precision Flexible Reamer Instrumentation. However, overall subject enrollment will not exceed 102.
Length of Study	24 months overall: 1. IRB/Ethics Committee approval if applicable, patients' identification and enrollment into the study. 2. Collection of baseline information. 3. Conduct data analysis, and draft the final report.
Materials and Methods	Clinical records of these patients will be studied from the Clinic database. The following information will be provided: • Instrument details for each case, descriptions will be documented. • Detailed complications summary; including date of occurrence, treatment and outcome/resolution. • Surgery/exam dates
Data Collection	Electronic or Hard Copy Case Report Forms
Statistical Reporting	Descriptive summaries will be used to generate an overall summary of clinical evaluation of the EZ Pass Suture Passer instrumentation and Precision Flexible Reamer instrumentation.
Scores/Performance Assessments	Survey/Operative Info/Complications
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]
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.

IV. Data Collection Overview

The following table indicates the necessary Case Report Forms to be completed at each given time point:

Form	Baseline	
	Pre-Operative	Post-Operative
Patient Information and Informed Consent, Inclusion/Exclusion Criteria, Demographic Evaluation	X	
Operative Information/Surgical Device Information		X
Complications/Adverse Events	As required	As required

V. Introduction and Purpose

The aim of this retrospective post-market follow-up study is to evaluate the safety and performance results of the EZPass Suture Passer and Precision Flexible Reamer Instrumentation. Both of these instruments are CE marked in Europe and FDA cleared. The EZ Pass Suture Passer has been CE-marked in Europe since 2015. The Precision Flexible Reamer has been CE-marked in Europe since 2013.

VI. Study Objectives

The primary objective of the study is to confirm the safety and clinical performance of the EZPass Suture Passer and the Precision Flexible Reamer Instrumentation.

Performance will be assessed through a post-operative survey conducted up to 14 days post-operatively.

Safety will be assessed by recording and analyzing the incidence and frequency of complications, adverse events, and intra-operative revisions.

VII. Study Design and Endpoints

Study Design

This is a single-center, retrospective enrollment, non-randomized, non-controlled, consecutive series post-market clinical follow-up study. The intent of the study is that subjects who have already had the surgical instrumentation used will be retrospectively enrolled in the study and data will be collected post-operatively. Subjects treated with the device will be identified and invited to participate in the study. Up to 102 subjects (51 subjects per arm of the study) will be enrolled into the study. This study will be conducted in the United States.

The study duration is dependent upon available retrospective data from the site and corresponds to time dedicated to:

- Obtain the Institutional Review Board (IRB)/Ethics Committee (EC) approval.
- Identify, obtain verbal or written informed consent, and retrospectively enroll subjects into the study.
- Collect baseline information available in medical records from the pre-operative interval to the post-op evaluation.
- Conduct data collection and analysis
- Draft the final report

Primary Outcome Measures/Endpoints

The primary endpoint for this study is the evaluation of the instrumentation safety from the results of the frequency of complications and adverse events from the time of admission until the time of follow-up post-operatively. The performance of the instrumentation will also be evaluated and collected in the form of an operative survey.

VIII. Study Population

The study population should be a consecutive series of subjects where the EZPass Suture Passer or Precision Flexible Reamer instrumentation was used. The following inclusion and exclusion criteria will be considered:

Inclusion Criteria

- EZ Pass Suture Passer: Intended as an open or arthroscopic instrument utilized in conjunction with a nitinol wire or nylon monofilament to aid in passing suture through soft tissue.
- Precision Flexible Reamer: This device is a hand held, or hand-manipulated device, intended to be used in ACL and PCL reconstruction surgeries and is intended for medical purposes to manipulate tissue, or for use with other devices in these surgeries

- Patient must be 18 years of age or older.

Exclusion Criteria

- Any use other than the approved uses indicated in the Instructions for Use (IFU).

IX. Study Device Information

EZ Pass Suture Passer:

The EZ Pass Suture Passers are comprised of a cannulated handle and shaft. A nitinol wire or monofilament can be fed through the handle and shaft to facilitate suture passing. The thumb wheels on the handle allow for the nitinol wire or monofilament to be advanced around the tissue, and then retracted. There are seven different shaft tips, which have varying orientations to be used in a variety of procedures. The shaft tip orientations include: 90° Up, 45° Up, 45° Dogleg Up, 70° Right, 70° Left, 30° Right, and 30° Left. To add stability and strength to the EZpass handle, a design change was implemented to secure the handle halves together using 8 stainless steel screws instead of the previously used ultrasonic welding. See Appendix for specific SKUs associated with the EZPass Suture Passers.

Figure 1: EZ Pass Suture Passers

Precision Flexible Reamer:

The unique design of the Precision Flexible Instrumentation provides an accurate

and reproducible system for anatomic ACL reconstruction. The curved guides and flexible drills facilitate tunnel placement at the true ligament origin, optimizing the native kinematics of the ACL graft. The dual plane geometry of the system offers the additional advantages of predictable and consistent tunnel position and length, without requiring hyperflexion of the knee during tunnel preparation.

The Precision Instrumentation allows various offset reference options along with alternative universal free-hand guides to accommodate surgeon preferences and anatomic variations and is compatible with numerous graft fixation options.

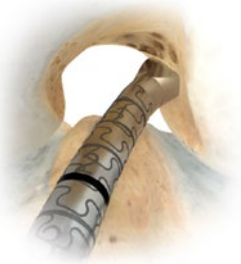

Figure 2: Precision Flexible Reamer

X. Study Procedures

a) Screening and Informed Consent

The investigator will screen clinic records to identify all consecutive patients that received treatment with the EZ Pass Suture Passer or Precision Flexible Reamer. Subjects who meet all of the inclusion criteria and none of the exclusion criteria will be invited to participate in the study, unless a waiver of consent is obtained from the IRB/EC. If no consent waiver is obtained, all patients must sign a written Informed Consent form approved by the IRB/EC.

b) Subject Identification

When a subject is enrolled, they will receive a unique case ID allocated by the investigator. The number will be allocated according to the chronological order of enrollment in the study. Subjects treated with both the EZ Pass Suture Passer and the Precision Flexible Reamer will require two different case IDs. The case ID must be recorded on all study documentation related to the enrolled patient. The investigator is responsible to provide all data as defined by the protocol to Zimmer Biomet.

c) Data Collection

Data will be recorded in a standardized way either electronically or on paper and copies are to be provided to Zimmer Biomet Clinical Affairs. Every effort must be made to ensure data submission to the Sponsor is made within 30 days of the data collection. The Investigator is responsible for the accuracy, completeness, legibility, and timeliness of all documented data for each individual subject. The Sponsor will maintain quality control systems, in accordance with the Sponsor's policies and procedures.

The following information will be collected and documented (if available) for each subject treated with the EZ Pass Suture Passer or the Precision Flexible Reamer and enrolled into the study:

Survey:

- Year of Birth
- Gender
- Height
- Weight
- Operative Side
- Year of Surgery
- Reason for use of the instrumentation

- Instrument/Implant details
- Operative Time (skin to skin)
- Blood loss
- Complications/adverse events (relation to either implant or instrumentation should be specified)

d) Data Management

Discrepancy checks will be done based on the data collected. If any discrepancies are identified, Zimmer Biomet's designated monitor will contact the site for clarification and correction, as necessary.

e) Completion of the Study

This study will be considered fully complete once post-operative data has been collected for 51 subjects who received treatment with the EZ Pass Suture Pass and 51 subjects who received treatment with the Precision Flexible Reamer.

XI. Reporting

The management of all study data received by the Sponsor will be the responsibility of the Sponsor or its Designee. The use or disclosure of all Protected Health Information (PHI) will comply with the Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR), as applicable. All information will be treated with strict adherence to professional standards of confidentiality and will be filed by the Sponsor under adequate security and restricted accessibility by clinical personnel. All electronic systems used to create, modify, maintain, or transmit study records will be validated according to 21 CFR Part 11. Reports and communications relating to study subjects will typically identify each subject only by the subject's assigned study subject Case ID number, date of surgery, operative side, and date or year of birth. All personally identifiable information on the source document CRFs will be pseudonymized in accordance with regional and/or national data privacy protection laws/regulations. The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to investigate the efficacy, safety, quality, and utility of the investigational product(s) used in this study.

Activities Required Prior to Initiation of the Study

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.

For this study, funding 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.

Institutional Review Board/Ethics Committee Protocol Approval

This study protocol must be submitted to and approved by the Investigator's Institutional Review Board (IRB) or Ethics Committee (EC). A copy of the IRB or EC approval letter must be submitted to the Sponsor. The letter should identify the following:

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

- Signature of IRB or EC.

ClinicalTrials.gov Registration

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

Clinical Data Collection/Submission

Summary of Case Report Form Data Collection

Study data will be collected on source documents which may include study-specific worksheets provided by the Sponsor. For subjects having bilateral arthroplasties, separate case report forms must be completed for each operative side.

The following source document/CRF completion guidelines should be followed:

- Complete carefully and accurately.
- Complete header information consistently across all case report forms for each individual study subject (when study-specific CRFs are used).
- Be sure that data on the source documents match that which is entered through the electronic data capture (EDC) system.
- Use the study subject's unique Case ID number assigned as instructed. Do not provide information that is not requested on the CRFs.
- Ensure that all fields are completed. For fields completed by the subject, efforts should be made to obtain any missing responses prior to the subject completing their visit.

Data Submission

Completed CRFs will be submitted directly to the Sponsor by electronic data capture and submission via a method approved by the Sponsor. Every effort must be made to ensure data submission to the Sponsor is made within 30 days of the visit completion.

Quality Assurance of Data

The Investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained. All electronic systems used to create, modify, maintain, or transmit electronic study records will be validated. The Sponsor will maintain quality control systems, in accordance with the Sponsor's policies and procedures.

Reporting Requirements

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 IRB or EC as required to maintain IRB or EC approval throughout the study, and will provide any required final reporting to the IRB or EC upon study completion/termination. A copy of all IRB or EC re-approval letters must be submitted to the Sponsor. If the IRB or 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 IRB or EC regarding any changes significantly affecting the conduct of the study, and/or increasing risk to the subjects.

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 IRB or EC requirements (whichever time period is greater). Measures shall be taken to prevent accidental or premature destruction.

Study records are defined as the 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, signed informed consents and all other study-related documents.

Management of Intercurrent Events

Failure to Obtain Informed Consent

Study data will not be collected until the Informed Consent has been signed and dated by the candidate, unless a waiver for consent has been issued by the IRB/EC. If a candidate does not wish to participate (does not sign and date the Informed Consent), data for that candidate will not be collected for this study.

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 on the Adverse Event Report form over the whole time of the investigation including information on the date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device. Further, the outcome of complications has to be documented and any changes in outcome are to be updated during the course of the study. 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 on the Adverse Event Report form over the whole time of the investigation including information on the date of onset, treatment and resolution, as well as assessment of both the seriousness and the relationship to the study device based on the evaluation of the investigator. The outcome of such complications has to be documented and any changes in outcome have to be updated during the course of the study. 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 and Device Deficiencies that could have led to a SADE to the Ethics Committee or Institutional Review Board if required by national regulations or by the IRB/EC.

Revision

In the event that removal of one or more of the study related components is necessary, the Investigator will determine the best treatment and/or revision method for the subject. Once the revision surgery has been completed, the Investigator or qualified Designee must complete an **Adverse Event Report** case report form.

Investigator Withdrawal

The Investigator can choose to withdraw a subject from the study if it is deemed to be in the subject's best interest or the subject does not consent to continue in the study after being informed of changes in the research that might affect them.

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 or Institutional Review Board, 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.

Study Termination

Study subject participation is expected to end upon completion of the Operative Survey for each subject.

If the Sponsor decides to terminate the study early, the Sponsor will inform the Investigators of the reason for early study termination. It is the responsibility of the Investigators to inform their IRB or EC as applicable according to local and national laws/regulations.

Modification of the Protocol

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 of the applicable IRB or EC must be obtained prior to implementation, if required according to the local and/or national laws/regulations.

XII. Safety Management – Medical Events/Adverse Events

Adverse events are required to be reported on the **Adverse Event Report** case report form. The completed **Adverse Event Report** case report form must be submitted to the Sponsor in a timely manner. 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 IRB or EC.

The following definitions are from ISO 14155:2020.

Classification of the Event

Adverse Event (AE):

An adverse event is any 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 investigational medical devices or comparators.

Serious Adverse Event (SAE):

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

- death,
- serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:
- a life-threatening illness or injury, or
- a permanent impairment of a body structure or a body function including chronic diseases, or
    - in-patient or prolonged hospitalization, or
    - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- led to fetal distress, fetal death or 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.

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.

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.

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 version of the risk analysis report.

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

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

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.

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.

Intensity of Symptoms

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.

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.

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.

Outcome Definitions

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

Resolved:

The adverse event has been resolved and/or no further treatment is required to treat the reported condition or illness.

Tolerated:

The adverse event will most likely never be resolved. The subject "tolerates" the illness or condition as a matter of life.

Pending:

Treatment or diagnostic studies were prescribed for the adverse event and the outcome of the adverse event is not yet known.

Reoperation:

The adverse event resulted in reoperation of the study joint, but the reoperation did not include removal of a study device.

Death:

The outcome indicates the subject died as a direct result of the reported adverse event.

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 .

XIII. Monitoring

Prior to initiating the clinical study, the Sponsor may conduct a site qualification visit to ensure the Investigator(s) 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, the Investigator must have a fully executed CTA and IRB or EC approval of the study protocol and the study Informed Consent.

During the course of the study, the Sponsor will conduct periodic central monitoring 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 case report forms, corresponding sections of study subject medical/hospital records, and any other documents relevant to the study.

XIV. Risk Analysis

This post-market clinical study is classified as minimal risk, and there are no additional or anticipated risks specific to study participation other than the potential loss of confidentiality. There are no experimental procedures in this study, and participation in this study is not anticipated to affect the medical treatment of enrolled subjects.

When used in accordance with product labeling, the risks associated with the use of the EZ Pass Suture Passer and the Precision Flexible Reamer are like that of any other suture assistance instrumentation. These risks are either general surgical or anesthesia risks or risks associated with the subject procedure/study device. Unanticipated adverse events can occur.

XV. Statistical Methods

Data collected in the study will be summarized descriptively. Descriptive summaries will form the basis of study reports and will generate an overall summary of the clinical evaluation of the EZPass Suture Passer and Precision Flexible Reamer instrumentation.

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 complications 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). Patient confidentiality will be protected at all times, and patient identifiers will not be included in data summaries

XVI. Quality Control & Quality Assurance

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

The Investigator will be required to permit representative(s) of the Sponsor's monitoring team to inspect all Case Report Forms 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 Case Report Forms.

The Clinical Investigation Plan will be provided to all participating study centers. The Investigators will be fully trained in the proper reporting and submission of trial data prior to patient enrolment. Completed Case Report Forms will be reviewed before entering the data into a central database by the Sponsor.

The Clinical Study Manager is responsible for generating data queries for missing or unclear data if needed. It is the responsibility of the Clinical Study Manager to ensure data quality.

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

XVII. Suspension or Premature Termination of the Clinical Investigation

The study Sponsor retains the ability to suspend or terminate this study before completion. If the study Sponsor decides to do so, the Sponsor will inform the Investigator(s) of the reason for early study termination. It is the responsibility of the Investigator(s) to inform their IRB/EC, as applicable, according to local and national laws/regulations.

XVIII. Amendments to the Clinical Investigation Plan

All amendments to this clinical protocol shall be agreed upon by the Sponsor and Investigator(s) and be recorded with a justification for the amendment. Approval of the IRB/EC that reviewed the original protocol must be obtained if required according to the corresponding regulations. In the case of an amendment to the protocol, the revision history will be documented in the Document History Section below.

XIX. Publication Policy

Both the Clinical Investigator and the Sponsor have the right to publish or allow the results of the clinical trial to be published. The Clinical Investigator recognizes

that the Sponsor has a special interest in the results of the clinical study and will submit manuscripts to the Sponsor prior to publication. If the Sponsor desires changes to be made, these are communicated to the Clinical Investigator within 30 days of submission. Pooled data may be used for training and meetings.

XX. Document History

Revision Number	Date	Description of Change	Person in Charge of Change
v4.0	15 Sep 2019	Initial Release	Kate Conrad
v4.1	27 Apr 2021	Updated to latest version of GBLF12202 Added elements to comply with ISO 14155:2020: Cover page – Added sponsor name and address Added Section I Contact List & Section II Abbreviations Added missing elements in Section III Study Synopsis Clarified Study Objectives in Section VI Added clarification to study design in Section VII Study Design Clarified study activities that occur throughout the study in Section X Study Procedures Added description of study completion in Section X, *part e)* Clarified reporting responsibilities of sponsor and investigator in Section XI Reporting Updated definitions of Adverse Events to match definitions in ISO 14155:2020 in Section XII Safety Management – Medical Events/Adverse Events Added Section XIII Monitoring and Section XIV Risk Analysis to comply with ISO 14155:2020 standard Clarified quality requirements in Section XVI Quality Control & Quality Assurance Added Section XVII Suspension or Premature Termination of the Clinical Investigation, Section XVIII Amendments	Branden Kemp

		to the Clinical Investigation Plan, Section XIX Publication Policy, and Section XX Document History to comply with ISO 14155:2020 standards.	

XXI. References

1. Clinical Investigation of medical devices for human subjects - Good Clinical practice. ISO 14155:2020, 2020.

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

Appendix A: SKUs and Descriptions

EZ Pass Suture Passer:

- 904050: EZ Pass 90 Deg Up
- 904051: EZ Pass 45 Deg Up
- 904052: EZ Pass 45 Deg Dog Leg Up
- 904053: EZ Pass 70 Deg Right
- 904054: EZ Pass 70 Deg Left
- 904055: EZ Pass 30 Deg Right
- 904056: EZ Pass 30 Deg Left
- 110007379: Suture Shuttle Monofilament
- 110007380: Suture Shuttle Kite
- 110008588: EZ Pass 70 Deg Left 10 Pack
- 110008589: EZ Pass 45 Deg Dog Leg Up 10 Pack
- 110008590: EZ Pass 45 Deg Up 10 Pack
- 110008591: EZ Pass 30 Deg Right 10 Pack
- 110008592: EZ Pass 30 Deg Left 10 Pack
- 110008593: EZ Pass 90 Deg Up 10 Pack
- 110008594: EZ Pass 70 Deg Right 10 Pack

Precision Flexible Reamer:

- 110009769: Precision MPF Nitinol SMA Guide Wire
- 110008343: Precision SMA Guide Wire 5 Pack
- 110004180: Precision Flexible Reamer 4.5mm Disposable
- 110004185: Precision Flexible Reamer 7.0mm Disposable
- 110004186: Precision Flexible Reamer 8.0mm Disposable
- 110004187: Precision Flexible Reamer 9.0mm Disposable
- 110004188: Precision Flexible Reamer 10.0mm Disposable
- 110004189: Precision Flexible Reamer 11.0mm Disposable
- 110004190: Precision Flexible Reamer 12.0mm Disposable
- 110010577: Precision Flexible Reamer 7.5mm Disposable

- 110010578: Precision Flexible Reamer 8.5mm Disposable
- 110010579: Precision Flexible Reamer 9.5mm Disposable
- 110010580: Precision Flexible Reamer 10.5mm Disposable
- 110010581: Precision Flexible Reamer 11.5mm Disposable