CLINICAL INVESTIGATION PLAN

CIP ID: CME2010-25H

NCT03672929

Allofit® IT with HXPE in Total Hip Arthroplasty

A multi-center, prospective, non-controlled post market surveillance study

Revision 01

02. February 2011

STUDY SPONSOR

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1 Contact Information/ List of Investigators

Sponsor:	Zimmer GmbH
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Statistical Analysis:	Zimmer Warsaw and Winterthur
Quality Assurance:	Dr. Hassan Achakri, Director Intl Clinical Affairs

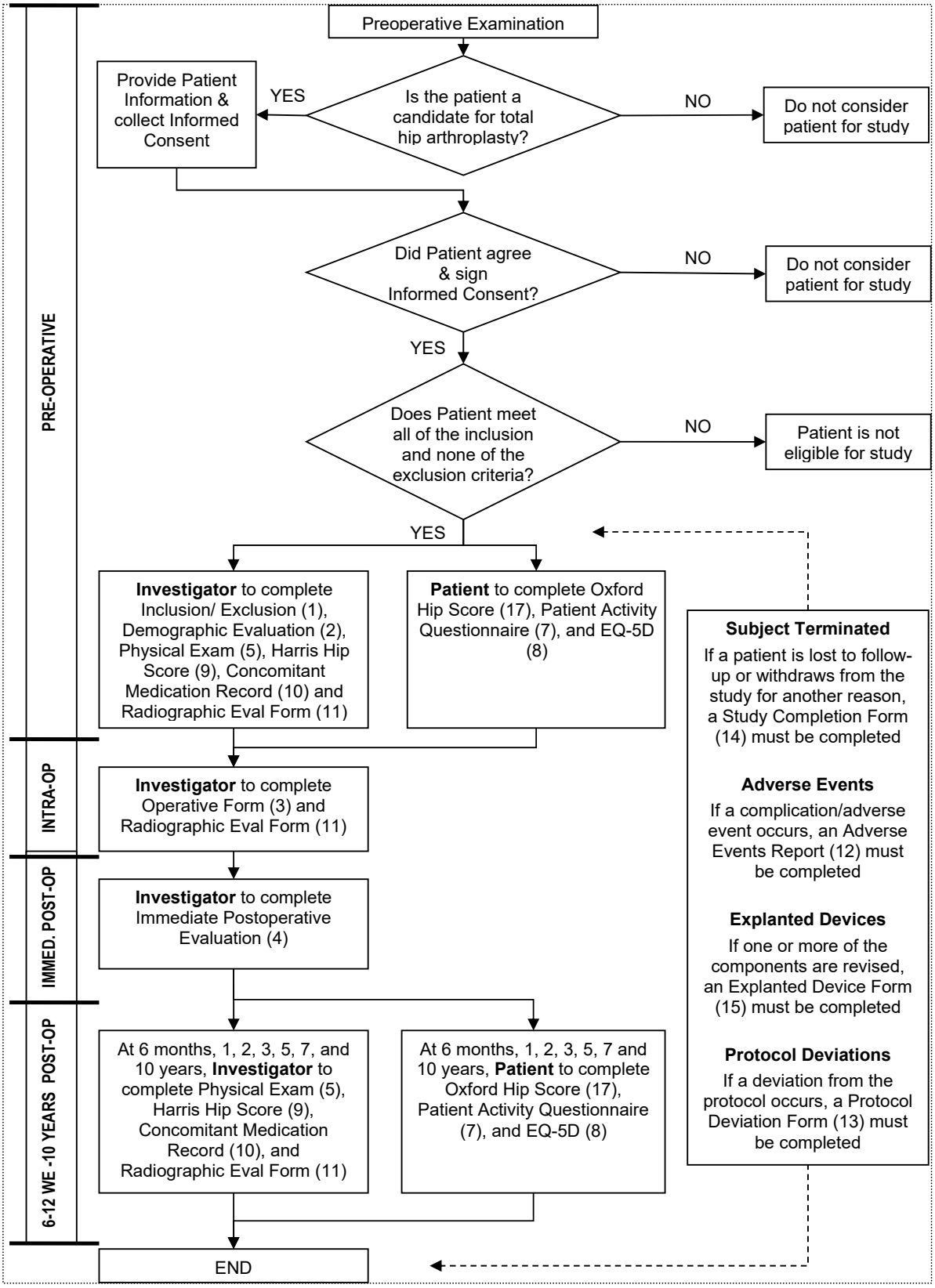
2 Study Synopsis

Title:	*Allofit*® IT with HXPE in Total Hip Arthroplasty A multi-center, prospective, non-controlled post market surveillance study
Sponsor:	Zimmer GmbH
Objectives/ Endpoints:	The objectives of this study are to obtain survival and outcome data on the *Allofit* IT Shell in combination with the *Longevity*® Liner when used in primary total hip arthroplasty. This will be done by analysis of standard scoring systems, radiographs and adverse event records. Data will be used to monitor pain, mobility and survivorship, and to confirm the safety and performance of the *Allofit* IT HXPE Bearing System. Safety will be evaluated by monitoring the frequency and incidence of adverse events. Performance will be determined by comparing the overall pain and functional performances, survivorship, subject quality-of-life and radiographic parameters of study subjects who received the *Allofit* IT HXPE Bearing System. Pain and functional performance will be measured using the Harris Hip Score, survivorship will be based on removal or intended removal of the device, subject quality-of-life will be determined by evaluation of the Oxford Hip Score, and radiographic parameters by analysis of x-rays.
Indication/ Target Population:	Patients, suffering from severe hip pain and disability requiring total hip arthroplasty, who meet the inclusion/ exclusion criteria (see Section 8).
Study Design:	Multi-center, prospective, non-controlled
Clinical Phase:	Post-market
Number of Subjects:	A total of 200 patients will be enrolled in this study
Length of Study:	12 years (2 year enrollment plus 10 years follow-up): follow-up visits at 6 months, 1, 2, 3, 5, 7, and 10 years post-operatively.
Study Device:	*Allofit* IT Shell in combination with:

	HXPE Articulation:	*Longevity* Liner with either Metal or Ceramic compatible Femoral Heads
	Femoral Component:	*Alloclassic*® *Zweymüller* Hip Stem or CLS® Spotorno®, *Avenir*® Müller Stem, or Fitmore® Stem
Scores:	Harris Hip Score (HHS); Oxford Hip Score; EuroQol (EQ-5D)	
Safety Assessments:	Safety will be assessed by appropriate recording and reporting of adverse events throughout the study. All system components are CE marked and commercially available.	
Statistical Analysis	Data collected will be summarized and reported to each participating Investigator. Statistical analysis is conducted by Zimmer or its designee.	
Documentation:	Paper / electronic	

This Clinical Investigation Plan is written in accordance with the ISO 14155 Standard for the Clinical Investigation of Medical Devices (part 1 and 2) [1;2].

3 Study Procedure Flowchart



4 Data Collection Overview

The following table indicates the forms to be completed at a certain time point:

Form Name	Pre-op	Surgery	Immediate Post-op	6 month (± 1 month)	1, 2, 3, 5, 7, 10 years post-op (± 2 months)
Informed Consent	X				
Inclusion/Exclusion Criteria (pages 1 & 2)	X				
Demographic Evaluation	X				
Operative Information (pages 1 & 2)		X			
Immediate Post-op Evaluation			X		
Physical Exam	X			X	X
Oxford Hip Score	●			●	●
Patient Activity Questionnaire	●			●	●
EQ-5D	●			●	●
Harris Hip Form	X			X	X
Concomitant Medication Record	X			X	X
Radiographic Evaluation (pages 1 & 2)	X	X		X	X
Adverse Event	^	^	^	^	^
Protocol Deviation	^	^	^	^	^
Study Completion	^	^	^	^	^
Explanted Device		^	^	^	^

X Form completed by Investigator or designee
● Form is completed by patient
^ Form is completed when indicated

5 Introduction

Total hip arthroplasty (THA) is a medical procedure where an arthritic, degenerative or fractured total hip joint is replaced with a prosthetic device. Since the inception of modern THA in 1961 [3], THA has become a widely accepted orthopedic procedure. In 2006, 533,000 total hip replacements were performed in Germany, France, Great Britain, and Italy [4] alone after non-operative treatment of a dysfunctional hip had failed to provide relief from painful and debilitating symptoms. Traditionally, THA was performed on patients between 60 and 75 years old [5]. Due greatly to continuous improvement in implant design, the range of THA patients has broadened to include both young and very old patients [5;6].

Major indications of THA include osteoarthritis, rheumatoid arthritis, avascular necrosis and hip fractures [6]. The THA surgical procedure involves replacing the head of the femur and acetabulum or socket with an artificial prosthesis. This system is composed of a femoral stem that is inserted into the femoral canal, a ball that attaches to the femoral stem, and an acetabular component or shell that replaces the acetabulum.

Ultimately, returning patients to a normal routine that affords them the freedom of mobility without pain and stiffness is the optimal goal of a THA procedure. Improving the overall quality of patients' lives, THA has an 84-90% patient satisfaction rate [3;7-9] and implant survival of up to 90% [10-16], as reported in published literature.

The *Allofit* IT Acetabular System incorporates a proven exterior shell structure possessing 15 years of history, with advanced bearing surfaces. Over 300,000 *Allofit* Acetabular Shells have been implanted since its initial clinical launch in 1994 [17].

Polyethylene was first used in articular joints in 1962 when Sir John Charnley implanted a hip prosthesis that included a high-density, high-molecular weight polyethylene component. After failed attempts with other materials, this high-density polyethylene proved adequate for low-demand patients. But as joint-replacement surgery became more common on younger and more active patients, demands increased and articulating surfaces required a more durable material.

Today, Ultra-High Molecular Weight Polyethylene (UHMWPE) is the material used in a majority of orthopaedic bearing components. The success of this higher molecular weight polyethylene is due to many favorable properties, including abrasion resistance, impact strength, low coefficient of friction, chemical inertness, and resistance to stress cracking.

As researchers gain a better understanding about the important role played by this bearing material in determining the longevity of prosthetic joints, and as the physical demands of bearing surfaces continue to increase, implant manufacturers are searching for ways to further improve the performance of polyethylene. The primary concern regarding polyethylene performance is wear damage and the impact of polyethylene wear debris on the arthroplasty, as well as on the surrounding tissue.

Although total hip replacements are known to survive more than 15 years [18-22] there is growing evidence showing that debris from polyethylene may be a limiting factor in the service life of some implants. [23-26] These concerns center around osteolysis and subsequent aseptic loosening, which have been reported to be associated with wear debris from polyethylene and other sources. [27;28] In total hip components, the wear particles typically generated are smaller than 1µm (micron) and are therefore referred to as submicron particles. These are generated by both abrasive wear and adhesive wear of polyethylene, as are larger particles.

Preliminary research shows that submicron particles are more likely to result in a host response than are larger particles. Furthermore, the greater the number of sub-micron particles the greater the host response. [28] A study found that 85 percent of the polyethylene particles from hips were less than 1µm in diameter [29]. Four percent of the particles in hips were larger than 2µm.

In addition to the raw material used, processing, design of the implants, and the sterilization and packaging of the implants are further factors that determine the ultimate performance characteristics of a given orthopaedic implant manufactured from polyethylene. Longevity HXLPE is manufactured by subjecting conventional UHMWPE to high-dose electron beam radiation, followed by melt-annealing. This process fully crosslinks broken molecular chains in the polymer, leaving virtually no free radicals to promote oxidation. This process creates a 3-dimensional structure that is more resistant to abrasion and a ten-fold wear rate reduction compared to conventional polyethylene control samples ([30])

Since 1995, numerous in vitro studies have been published suggesting improved wear resistance (increased surface hardness) and increased resistance to creep (decreased ductility) of crosslinked polyethylene compared to non-crosslinked conventional polyethylene ([31-33]). Clinical reports in the literature have confirmed decreases in abrasive wear, creep, and generation of particle wear debris, as demonstrated by the data reported in the selected literature ([34-38]) on Longevity HXLPE liners used in Trilogy shells.

The subject of this clinical investigation is the *Allofit* IT Shell in combination with the *Longevity* Liners in primary total hip arthroplasty. This system consists of a cementless modular Acetabular Shell, a modular liner, and a modular femoral head. The characteristics of this THA system may allow for reduction in wear and osteolysis as compared to other approved and marketed THA systems and thus increase the expected implant life.

6 Study Objectives

The objective of this study is to obtain survival and outcome data on the *Allofit* IT Shell in combination with *Longevity* Liners in primary total hip arthroplasty. This will be done by analysis of standard scoring systems, radiographs and adverse event records. Data will be used to monitor pain, mobility and survivorship, and to confirm the safety and efficacy of the *Allofit* IT with HXPE in primary total hip arthroplasty.

a) Safety:

   Will be evaluated by monitoring the frequency and incidence of adverse events (AE), serious adverse events (SAE), adverse device effects (ADE) and serious adverse device effects (SADE)

b) Efficacy:

   Will be determined by comparing the overall pain and functional performances (based on the Harris Hip Scoring system), survivorship, subject quality-of-life and radiographic parameters (radiolucencies, osteolysis, subsidence, cup migration, change in cup angle and change in femoral shaft angle) of study subjects who received the *Allofit* IT Acetabular System

   a. Pain and Functional Performance:
      Measurements will be based on the Harris Hip Scoring (HHS) System [39]

   b. Subject Quality-of-Life:
      Will be determined by the Oxford Hip Score [42] and the EQ-5D [41]

   c. Radiographic parameters:
      X-rays will be evaluated for radiolucencies, cup migration, osteolysis, subsidence, and change in cup angle

   d. Survivorship:

Based on removal or intended removal of the device and will be determined using the Kaplan-Meier method

The data will meet Zimmer's obligation to collect device vigilance and post market surveillance information for European regulatory bodies.

7 Study Design

7.1 General

The study design is a multi-center, prospective, non-controlled, consecutive cohort post-market clinical follow-up study involving orthopedic surgeons skilled in total hip arthroplasty and experienced with the implants subject of this study. In total, 5 centers will be involved. This number of clinical sites will permit assessment of the consistency among a multitude of Investigators. A total number of 200 subjects will be included in the study. It is anticipated that each clinical site will enroll 40-60 eligible study subjects, who have provided written informed consent.

Ethics Committee (EC) approval for each site has to be obtained prior to conducting this research. Sequentially, all eligible patients will be offered study enrollment at each center to avoid potential selection bias. All potential subjects will be required to participate in an informed consent process and sign an EC approved written informed consent prior to study enrollment. It is anticipated the enrollment period may be 12 months or longer to assure an adequate number of cases at each site.

Each case enrolled will receive an *Allofit* IT HXPE Bearing System. The study is designed to be prospective to ensure that the study population is representative of the type of population that the device is intended to treat. The subjects included will be candidates for an *Allofit* IT HXPE Bearing System. All system components are CE-marked and commercially available. Patients will be selected according to the subject selection criteria described in section 8.

All subjects will undergo preoperative clinical, functional and radiographic evaluations, total hip arthroplasty, immediate post-operative evaluations and post-operative clinical, functional and radiographic evaluations at 6 months (± 1 month), 1 year (± 2 months), 2 year (± 2 months), 3 year (± 2 months), 5 year (± 2 months), 7 year (± 2 months), and 10 year (± 2 months).

7.2 Study Duration

After the initial visit followed by the surgery, the patient is expected to participate in the study for a time period of 10 years. Cases will be recruited during a period of 24 months, and the study will last until complete collection of the 10 years follow-up data.

8 Study Population

The study population will be comprised of 200 males and females who require primary total hip arthroplasty. Subjects will be enrolled at 5 investigative centers. Subjects must be geographically accessible throughout the study and be willing and able to attend required follow-up appointments. Candidates who express interest in study participation will be offered informed consent, and eligibility will be determined based upon the inclusion/exclusion criteria.

A. Inclusion Criteria

- Patient is 18 to 75 years of age, inclusive.
- Patient is skeletally mature.
- Patient qualifies for primary unilateral or bilateral total hip arthroplasty (THA) based on physical exam and medical history including the following:
    - Avascular necrosis (AVN)
    - Osteoarthritis (OA)
    - Inflammatory arthritis (i.e. Rheumatoid arthritis)
    - Post-traumatic arthritis
- Patient has no history of previous prosthetic replacement device (any type, including surface replacement arthroplasty, endoprosthesis, etc.) of the affected hip joint(s).
- Patient has a Harris Hip Score <70 in the affected hip
- Patient is willing and able to provide written informed consent.
- Patient is willing and able to cooperate in the required post-operative therapy.
- Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent.
- Patient has participated in the Informed Consent process and has signed the Ethics Committee approved informed consent.

B. Exclusion Criteria

- The patient is:

    - A prisoner
    - Mentally incompetent or unable to understand what participation in the study entails
    - A known alcohol or drug abuser
    - Anticipated to be non-compliant.
- The patient has a neuromuscular disorder, vascular disorder or other conditions that could contribute to prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- The patient has a vascular (large and small vessel disease) insufficiency.
- The patient has a neurologic condition in the ipsalateral or contralateral limb which affects lower limb function.
- The patient has a diagnosed systemic disease that could affect his/her safety or the study outcome.
- The patient is known to be pregnant.
- The patient is unwilling or unable to give informed consent, or to comply with the follow-up program.
- The patient has received an investigational drug or device within the previous 6 months.
- The patient has an active or latent infection in or about the affected hip joint or an infection distant from the hip joint that may spread to the hip hematogenously.
- The patient has insufficient bone stock to fix the component. Insufficient bone stock exists in the presence of metabolic bone disease (i.e. osteoporosis), cancer, and radiation. Note: Dual Energy X-ray Absorptiometry (DEXA) may be used to assess the presence of adequate bone stock.
- The patient has osteoradionecrosis in the operative hip joint
- The patient has a known sensitivity or allergic reaction to one or more of the implanted materials.
- The patient has known local bone tumors in the operative hip.
- The patient is Grade III obese with a Body Mass Index (BMI) > 40.

9 Study Outcome Measures/ Endpoints

The aim of the *Allofit* IT with HXPE is to restore function and gait, and alleviate pain in the long-term.

9.1 Outcome Measures/ Endpoints

- Pain and Functional Performance (HHS) [39]

- Safety (adverse events)
- Survivorship (Kaplan Meier)
- Subject Quality-of-Life (Oxford Hip Score) [42] and EQ-5D [41]
- Radiographic parameters (Radiolucencies, cup migration, osteolysis, subsidence, and change in cup angle

10 Data Collection & Management

10.1 Case Report Forms

The data will be collected on study specific Case Report Forms (CRF) provided by the Sponsor (see Appendix B).

It is a requirement that two sets of CRFs are completed for patients having bilateral hip replacement.

The following information and data will be collected on all hips entered into the study:

The **Inclusion/Exclusion Criteria** Form (form 1) determines if the patient meets all inclusion criteria and none of the exclusion criteria.

The **Demographic Evaluation** Form (form 2) collects demographic data, diagnosis, and relevant medical and surgical history.

The **Operative Information** (form 3A and B) collects details on the surgical approach, anesthesia, OR time, blood loss and the implant components.

The **Immediate Postoperative Evaluation** Form (form 4) is completed at the first post-operative appointment. This form gathers data on length of hospital stay, discharge disposition, and deep vein thrombosis (DVT) prophylaxis.

The **Physical Exam** Forms (form 5) collects the patient weight, leg length discrepancy, Trendelenburg and Charnley Classification.

The **Oxford Hip Score** (form 17) consists of 12 questions specific to the hip and is a patient completed form [42].

The **Patient Activity Questionnaire** (form 7) collects data on patient activity level and patient satisfaction of the outcome. This form is completed by the patient.

The **EQ-5D (EuroQol) Questionnaire** (form 8) is completed by the patient and assesses his/her general health status. The EQ-5D is used to derive a quality of life index used for health economics considerations [41].

The **Harris Hip** Form (form 9) ascertains the patient's level of pain, activity level and post surgical satisfaction. This form should be completed by the Investigator [42].

The **Concomitant Medication(s)** Form (form 10) collects details on the medication given to the patient.

The **Radiographic Evaluation 1 and 2** Form (form 11A and B) is completed by the Investigator or its designee upon review of the protocol required x-rays.

The **Adverse Events Report** (form 12) is completed as needed for each patient complication noted. A separate form is completed for each complication. Multiple complications per visit are to be recorded on one form.

The **Protocol Deviation** Form (form 13) collects information on the reason for the protocol deviation.

The **Study Completion** Form (form 14) is completed when the patient completes the study. If there is a change to the active participation of a patient in the study, it is necessary to complete this form. Examples include lost-to-follow-up, death, refusal to return for an assessment, or withdrawal from a study.

The **Explanted Device** Form (form 15) is completed by the Investigator or his/her designee and details reason and results on explanted devices.

10.2 General Instructions for Completion of Case Report Forms

The data will be collected on study specific Case Report Forms (CRF) provided by the Sponsor (see Appendix B).

- The Investigator will be responsible for the accuracy and completeness of the CRFs.
- All data must be completed in the pre-defined CRFs.
- No items should be left blank unless directed.
- CRFs are to be completed with black or blue ink.
- CRFs have to be legible.
- Corrections have to be identified by initials and date.
- The Investigator or designee has to sign and date the CRFs where indicated.

10.3 Patient Privacy and Identification

When a subject is considered eligible for entry into this study, each hip enrolled will receive a unique case ID (maximum of 6 digits) allocated by the Sponsor. The case ID must be recorded on all study documentation related to the enrolled device. Subjects with

bilateral hip replacements will require two sets of Case Report Forms and thus will have two different case IDs.

All patient related data documented on the Case Report Forms as well as on any additional self assessment form, will be kept anonymously. On these forms the patients will only be tracked by their initials, the date of birth and a patient number. This code can only be decoded by the study centre itself.

10.4 Submission of Case Report Forms / X-Rays

Each completed CRF has to be photocopied or scanned and submitted to the Sponsor. The original CRFs must be kept in the Investigator's CRF folder. Copies of the original X-Ray film taken at the site during the indicated evaluations should be made available to the Sponsor upon request. The CRFs can be submitted by

- E-MAIL: francois.geiger@zimmer.com
- POST MAIL: Zimmer GmbH
  International Clinical Affairs
  Sulzerallee 8
  P.O. Box
  CH-8404 Winterthur
  Switzerland

10.5 Monitoring Visits

Prior to initiating any clinical use of the devices under study, Zimmer will conduct a site initiation visit to ensure the Investigators understand the use and application of the devices under study, the Investigators and staff have adequate time and resources to implement and follow the Clinical Investigation Plan, and ensure the Investigators have access to the target patient population under study. Prior to initiation of the study, the Investigator must have a fully executed Clinical Trial Agreement and EC approval of the Clinical Investigation Plan and Informed Consent. Further monitoring visits (including the closing visit) will take place as needed.

The Study Monitor occasionally requires access to the patient records, Patient Consent Forms, original Case Report Forms, radiographs and relevant office notes during visits for monitoring purposes.

10.6 Data Entry

The Sponsor will enter and verify all data in a central database.

The management of all data will be the responsibility of Zimmer or its designee. The use or disclosure of all protected health information will comply with the data protection act. All

information will be treated with strict adherence to professional standards of confidentiality. Data analysis will be conducted at the Corporate Offices in Warsaw, Indiana, USA or Winterthur, Switzerland. All data will be encrypted and all personnel in the data management team will comply with the data protection act.

Each participating Investigator will receive study reports on their own data and the collated data for the whole study group. Study metrics, e.g. summary tables, graphical output and descriptive statistics will be produced and may be available as hard copy. Strict confidentiality of individual hospital data will be maintained.

11 Study Procedure

11.1 Offer Study Participation

For each consecutive patient presenting as a candidate for total hip arthroplasty, study participation shall be offered. Based on the patient response, the patient may be invited to enroll in the clinical study. Prior to patient enrollment, the patient must participate in the Informed Consent process, participate in the inclusion/exclusion process, and sign the Ethics Committee (EC) approved Informed Consent.

11.2 Patient Enrollment Log

A Patient Enrollment Log shall be maintained throughout the study and is included in the Investigator Binder. All patients who are screened and offered study participation and/or are participating in the inclusion/exclusion process and/or are consented for the study shall be entered in the log regardless of study eligibility. Finally subjects enrolled in the study must be sequentially entered in the log as well.

11.3 Determination of Eligibility

Patient eligibility for enrollment will be determined for consenting candidates based upon the inclusion/ exclusion criteria. Patients must meet all of the inclusion criteria and none of the exclusion criteria in order to be offered enrollment into the study. Determination of eligibility may include an interview to assess significant patient medical/ surgical history, history of present illness/ injury, evaluation of present pain and functional capacity, and a radiographic assessment. Eligible patients will be offered enrollment into the study. For the purposes of this clinical study, patients will be considered subjects after enrollment has been completed.

11.4 Informed Consent

All patients must sign a written Informed Consent (Appendix C) approved by the Ethics Committee (EC), prior to participate in the inclusion/ exclusion criteria screening process

and thus prior to be enrolled in the clinical study. This signed document is required for patients to be enrolled in the study and to receive the devices as defined by this protocol and will further serve as documentation of an offer to participate in the study for those patients who elect not to do so. No patient will be enrolled without having signed the Informed Consent.

11.5 Baseline/Pre-operative Assessment

Data required for completion of the pain, functional and quality-of-life evaluations as well as the radiographic evaluations will be collected preoperatively. All subject data will be used in the analysis of overall pain and functional performance, survivorship, and radiographic parameters and will include the following Case Report Forms (CRF):

1. Inclusion / Exclusion Criteria Form
2. Demographic Evaluation Form
3. Physical Exam Form
4. Oxford Hip Score Form
5. Patient Activity Questionnaire Form
6. Harris Hip Form
7. Concomitant Medication Record
8. Radiographs Evaluation Form (standing anteroposterior (AP) and standard lateral views of the operative hip)
9. EQ-5D Form

11.6 Surgical Technique

The surgical technique for the *Allofit* IT Acetabular System (Doc. No. 06.01651.012) is provided in the Investigator Binder.

11.7 Surgery until Discharge Assessment

Post-operative management for study subjects will follow the standard-of-care for patients undergoing total hip arthroplasty. Required surgical and discharge data will include, but is not limited to the following:

1. Operative Information Form
2. Immediate Post-op Evaluation Form
3. Radiographs Evaluation Form (supine anteroposterior (AP) view of the operative hip)
4. Adverse Events
5. Protocol Deviations

11.8 Follow-up Procedures (Data Collection)

Data required for completion of the pain, functional and quality-of-life evaluations as well as the radiographic evaluations will be collected postoperatively at 6 months (± 1 month), 1 year (± 2 months), 2 year (± 2 months), 3 year (± 2 months), 5 year (± 2 months), 7 year (± 2 months), and 10 year (± 2 months). Post-discharge data collection will include, but is not limited to the following:

1. Physical Exam Form
2. Oxford Hip Score Form
3. Patient Activity Questionnaire Form
4. Harris Hip Form
5. Concomitant Medication Record
6. Radiographs Evaluation Form (standing anteroposterior (AP) and standard lateral views of the operative hip)
7. EQ-5D Form
8. Adverse Event Form (if any)
9. Protocol Deviation Form (if any)
10. Explanted Device Form (if any)
11. Study Completion Form (if the case)

Patient follow-up is expected to continue through 10 years of follow-up for each case although it is expected that a few subjects may succumb to other medical problems or otherwise lost to follow-up prior to completion of the 10 years of follow-up. All subject data will be used in the analysis of overall pain and functional performance, survivorship, and radiographic parameters. Data will continue to be collected until the subject completes the study, is lost to follow-up, one or several devices are removed due to revision, or the study is otherwise closed.

11.9 Minimization of Subjects Lost to Follow-up

Subject follow-up is extremely important for the conduct of a clinical study. The expectation is to maintain the highest rate of follow-up compliance possible throughout this study. In an effort to minimize *lost to follow-up* study subjects, the following recommendations and/or study requirements are essential to ensure proper patient selection and compliance:

1. Patient Eligibility: Subjects will be selected according to patient eligibility criteria detailed in Section 8 and are expected to return for all follow-up visits.

2. Patients Counseled: Patients will be counseled during the informed consent process on the importance of returning for follow-up visits.

3. Patient Exclusion: Patients who are not willing to return for study required follow-up visits and/or are not willing to comply with the follow-up schedule will not be considered for enrollment in the study.

4. Subject Due Listings: In addition to proper patient selection, Zimmer will provide subject due notices to the sites on a regular basis in order to track each study participant and monitor adherence to the required follow-up visit timeframes. The subject due listings will facilitate scheduling the subjects for their return office visits.

5. Financial Hardship: If during the course of the study it is determined that a subject is experiencing a financial hardship that prevents the subject from returning for follow-up visits, Zimmer should be notified to discuss possible financial assistance which may be available to the subject.

6. Contact Tracking: Attempts to contact subjects will be documented. It is recommended that the first three attempts be made by telephone.

Recommended Contact Attempts

If	**then**
A response is not received from the three phone calls	The Investigator should send a letter to the subject explaining the follow-up agreement per the informed consent.
A response is not received from the Investigator's letter	The Investigator should send a certified letter to the subject.
A response is not received from the Investigator's certified letter	The Investigator should use any additional contacts provided by the subject to contact the subject.
If all attempts to contact the subject are unsuccessful or the subject is contacted and chooses to withdraw from the study	The Study Completion CRF will be completed and will specify the reason the subject is no longer participating in this study.

11.10 Radiographic Definitions and Methods

All radiographic evaluations performed according to the protocol will be reviewed by the Investigator at the time of the evaluation for assessment of post-operative adverse events as well as for standard patient management purposes. If a radiographic adverse event is identified by the Investigator during the course of the investigation, the Investigator must document the event and report the radiographic findings on Adverse Event Report CRF for Sponsor review. In addition, assessments of radiographic films for evidence of

radiolucencies, osteolysis, subsidence, acetabular cup migration, and change in acetabular cup angle, will be performed.

11.10.1 Required Radiographic Views

Standing anteroposterior (AP) and standard lateral radiographs of the operative hip are required to be captured before surgery and at 6 months, 1, 2, 3, 5, 7, and 10 years post-operatively. At the immediate post-operative interval, only a supine AP view of the operative hip is required.

Every effort should be made to obtain all radiographic views for every interval at the same institution to maintain consistency. However, if radiographs are completed at a different institution within the required interval and copies or originals are available, they may be used for study submission provided they meet the required specifications.

11.11 Reporting of Adverse Events and Adverse Device Effects

Adverse Events and Adverse Device Effects have to be documented during the whole course of the study (for details see Section 14).

12 Implant Information

12.1 Description of the Device

A. Investigational Devices

1. *Allofit*® IT Acetabular Shell
2. *Longevity*® Liner

B. Investigational Device Description

1. *Allofit* IT Acetabular Shell

   The shells are mainly made from Titanium (Protasul®-Ti Alloy). The shells are available with or without screw holes. The Allofit IT Shells have no screw holes, the Allofit-S IT Shells allow for the use of screws to provide additional fixation and security, particularly in those cases where acetabular bone stock is deficient. Only 6.5 mm diameter *Allofit* Screws (Catalog numbers 4301-07-xxx) and 6.5 mm diameter *Trilogy*® screws (Catalog numbers 00-6250-065-xx) should be used with the *Allofit*-S IT Acetabular Shell. Screw holes that are not utilized for fixation and the dome hole may be closed with optional plugs.

   The *Allofit* IT Acetabular Shell is packaged without a liner. The selection of an appropriate liner is required to complete the acetabular component.

2. *Longevity* Liner

   The Longevity Liners are made from long Polyethylene chains $(CH2)_n$ which are cross-linked by E-beam irradiation. The Longevity Liners are secured in the shell by a snap feature. Anti-rotation tabs provide rotational stability. The inner diameter of the liner must match outer diameter of the selected femoral head.

C. Intended use / Surgical Technique

   Total Hip arthroplasty is intended to reduce pain and increase hip mobility. A system consisting of a stem, a femoral head and a cup (= shell + liner) is used for the treatment of degenerative diseases or trauma of the hip. The articulation is comprised of a femoral head and a corresponding liner. All components are intended for single use only.

   The surgical technique for the *Allofit* IT Acetabular System (Doc. No. 06.01651.012) can be found in the Investigator Binder.

12.2 Risks

The risks associated with the use of the *Allofit* IT Acetabular System are similar to those with the use of other standard acetabular hip systems when used for the same clinical indication. These risks are categorized as those anticipated to be related to general surgical risks, total hip arthroplasty risks, or those potential risks associated with the investigational system. Unanticipated adverse events may occur as well.

13 Statistical Considerations/ Evaluation

13.1 Analysis Objectives

The assessment of efficacy for subjects receiving the total hip replacement system will be determined using the overall pain score and functional performance. Clinical success will be defined as a modified Harris Hip score of > 80 that included a rating of ‘mild’, or ‘no pain’; a failure will be defined as a modified Harris Hip score < 80. Any study hip that required a subsequent surgical intervention where a stem head, cup, or liner was removed, or where a removal was planned, was considered a failure regardless of the Harris Hip score. Success rates will be expressed as percentages and primary summary results will be presented in tables which will contain the number and percentage of patients classified as a clinical success for the treatment group.

The assessment of safety will be evaluated by monitoring the frequency and incidence of adverse device effects in investigational subjects. As part of the safety profile, a survival analysis will be done.

The endpoints that contributed to the composite success will be summarized separately, that is, the Harris Hip Scores, both function and pain. Additionally, there are measures of interest which will be used to assess the investigational device such as radiographic success, all components included in the assessment of radiologic success, the Oxford Hip Score patient satisfaction scores, patient activity scores, concomitant medication usage, and incidence of adverse events.

13.2 Variables for Analysis

Key demographic, baseline and peri-operative characteristics will be summarized for the *Allofit* IT Acetabular Shell with a *Longevity* Liner, both overall, and for each investigative site. Demographic, baseline, and peri-operative data will include:

- Demographics
- Age
- Gender
- Body Mass Index
- Alcohol use
- Tobacco use
- Baseline Characteristics
- Preoperative Harris Hip Pain Score
- Preoperative Harris Hip Functional Score
- Preoperative Activity Level
- Concomitant Medication
- Preoperative Radiographic assessment
- Diagnosis
- Oxford Patient Satisfaction
- Peri-Operative
- Surgery time
- Blood loss
- Hospital stay - defined as the date of discharge minus the date of surgery

Summaries will be done and compared preoperatively and at 6-12 weeks, 12 months, and 24 months initially. Long-term follow-up will be further compared at 3, 5, 7, and 10 years postoperatively.

For dichotomous variables and for variables with more than two responses, the number and percentage of patients in each category will be presented for the treatment. For continuous variables, descriptive statistics including counts, means, medians, standard deviations, minima, and maxima will be presented for the treatment group.

13.3 Sample Size Justification

Sample size for the Allofit IT HXPE Study was estimated using the McHugh and Le method [43] with an alpha (Type I) error level of 0.05, a non-inferiority margin of 5.2% (δ), and an assumed survival rate of 90% at 10 years from ODEP.

The confidence limit approach, as discussed by McHugh and Le [43], can be used to calculate this sample size estimate. Specifically, we infer that the non-inferiority margin provides the absolute precision (5% δ) for the difference between the fixed rate in the historical control group and the rate estimated for the experimental group over the course of the study. Sample size estimation utilizes the following formula:

$$\delta\sqrt{n} = Z_{1-\alpha}\sqrt{\frac{p_{\exp}(1-p_{\exp})}{w_{\exp}} + \frac{p_{HC}(1-p_{HC})}{w_{HC}}}$$

where δ represents the non-inferiority margin, n represents the group size, p_{exp} represents the rate in the experimental group, p_{HC} represents the rate in the historical control group, w_{exp} represents a weight (i.e., allocation weight) to accommodate unequal group size for the experimental group, w_{HC} represents the allocation weight to accommodate unequal group size for the historical control group, and $Z_{1-\alpha}$ represents the value of a standard normally distributed random variable corresponding to a cumulative probability of one minus alpha (0.05).

When adjusting for a ceiling in the calculation, and added attrition rate of 20% there is a sample size requirement of 195 for the experimental group. A sample size of 200 is therefore planned for enrolment in this study.

Sample size was estimated using SAS v. 9.1.3 for Windows.

14 Management of Incurrent Events

14.1 Definitions

As defined by EN ISO 14155-1 [1] and ISO 14155-2 [2]:

Adverse Event

An Adverse Event is defined as any untoward medical occurrence in a subject. This definition does not imply that there is a relationship between the adverse event and the device under investigation.

Adverse Event is synonymous with complication or medical event.

Serious Adverse Event

A Serious Adverse Event is defined as an Adverse Event that:

- leads to death,
- leads to a serious deterioration in the health of the subject that
    1) resulted in a life –threatening illness or injury,
    2) resulted in an impairment of a body structure or a body function,
    3) required in-patient hospitalization or prolongation of existing hospitalization,
    4) resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function,
- leads to fetal distress, fetal death or a congenital abnormality or birth defect.

Adverse Device Effect

An Adverse Device Effect is defined as 'any untoward and unintended response to a medical device'. This definition includes any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device. This definition includes any event that is a result of a user error.

Serious Adverse Device Effect

A Serious Adverse Device Effect is defined as 'an Adverse Device Effect that has resulted in any of the consequences characteristic of a Serious Adverse Event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune'.

14.2 Reporting and Documentation of Adverse Events and Adverse Device Effects

Adverse Events and Adverse Device Effects have to be documented on the Adverse Events Report Form over the whole time of the investigation. Further the outcome of such complications has to be documented and any changes in outcome to be updated during the course of the study.

14.3 Reporting and Documentation of Serious Adverse Events and Serious Adverse Device Effects

Serious Adverse Events and Serious Adverse Device Effects have to be documented on the Adverse Events Report Form over the whole time of the investigation. The outcome of

such complications has to be documented and any changes in outcome to be updated during the course of the study.

14.4 Recommended Revision Procedure

14.4.1 Revision Methods

Standard total hip replacement and revision methods will be utilized in the event of a device failure resulting in revision of one or more of the System Components (i.e. acetabular shell, liner, head, or femoral stem).

14.4.2 Prior to Revision Surgery

Prior to revision surgery, the Investigator must evaluate the acetabular and femoral components for any evidence of migration, change in cup angle, radiolucencies or osteolysis by comparing the immediate post-operative and most recent post-operative radiographs of the operative hip.

14.4.3 During the Revision Surgery

During the revision surgery, the Investigator must carefully inspect the surgical site for any evidence of acetabular or femoral instability, excessive surface wear or the presence of any other acetabular or femoral component damage. If it is believed the acetabular or femoral components are unstable for any reason or damaged in any way, it is recommended the unstable/damaged acetabular or femoral component(s) be removed and revised.

14.4.4 Explanted Investigational Device Analysis

In the event of an investigational device revision, all components revised should be returned to Zimmer for analysis. The Investigator must notify the study manager prior to the return of any device.

For used, contaminated devices, immerse the implant in 10 percent neutral buffered formalin, label the implant container to identify the catalog number, Investigator name, Case ID, date of removal, and include a statement indicating the implant is from an IDE study.

Properly prepared specimens are to be sent to:

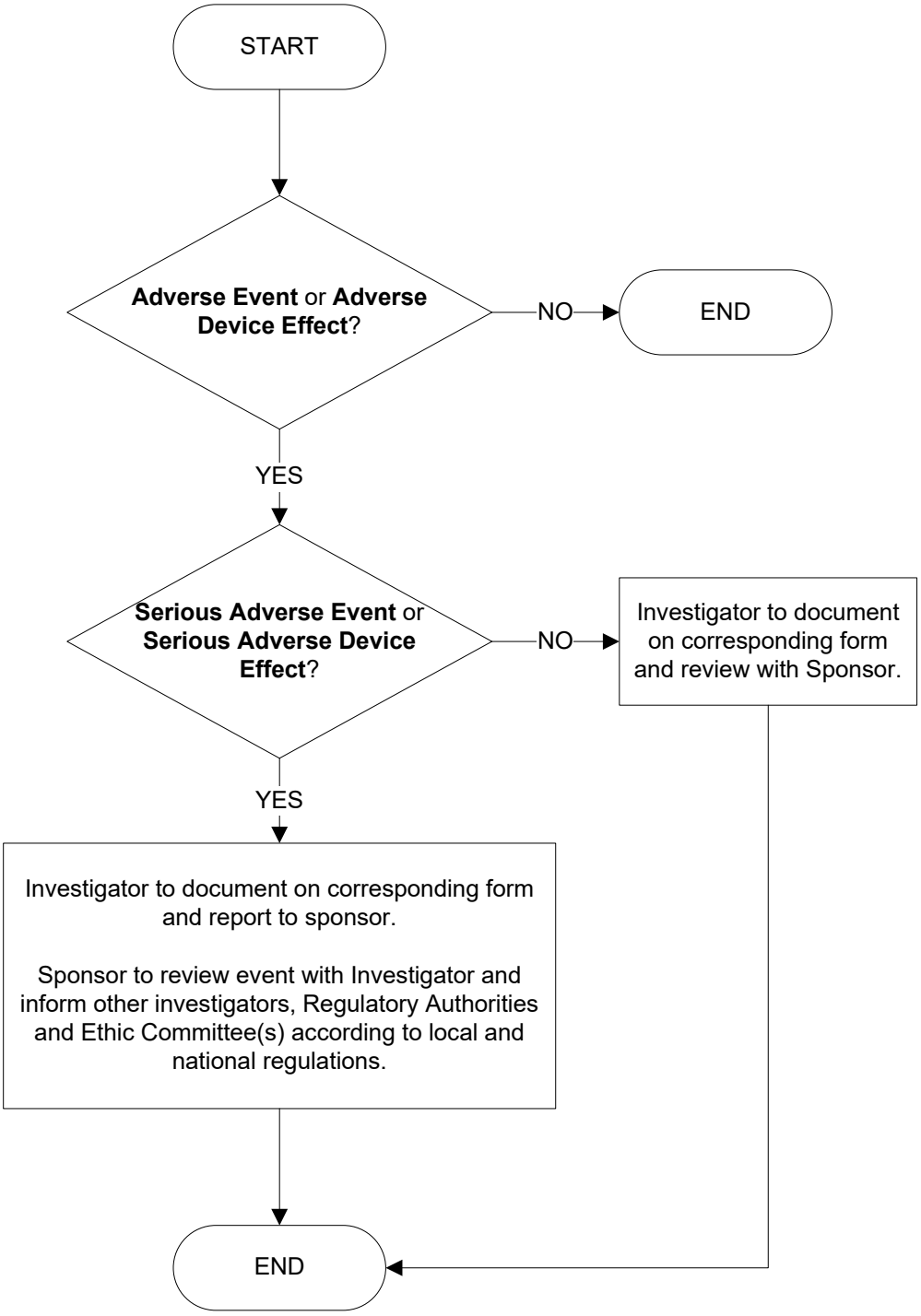
Zimmer GmbH
International Clinical Affairs
François Geiger
Cost Center 113505
Sulzerallee 8
CH-8404 Winterthur
Switzerland

Once the analysis is complete, a copy of the report will be maintained in the study subject record by Zimmer International Clinical Affairs and a copy will be sent to the Investigator for his/her study records. A summary of all detailed explant reports will be provided in the Annual Reports.

All SAEs and SADEs have to be reported to the Clinical Study Manager as soon as possible by sending a copy of the Adverse Events Report Form either by fax to or e-mail to:

Zimmer GmbH
International Clinical Affairs
Sulzerallee 8
P.O. Box
CH-8404 Winterthur
Switzerland
Tel. +41 52 262 79 71
Fax +41 52 244 34 90
francois.geiger@zimmer.com

14.5 Documentation and Reporting Flow Chart



14.6 Patient Withdrawal

Subjects may withdraw from the study at any time. If possible, a final evaluation will be completed for all subjects who no longer wish to participate in this investigational study. The reason for the subject withdrawal must be documented on the Study Completion case report form.

14.7 Lost to Follow-up

Patients will be considered lost to follow-up after they have missed a visit and a reasonable number of attempts to locate and evaluate them have failed. This has to be documented on Study Completion Form. In particular the reason must be documented.

14.8 Protocol Deviation

The Investigator should not deviate from the agreed Clinical Investigation Plan unless it is to eliminate hazard to the patient. However, any deviation from the Clinical Investigation Plan has to be documented on the Protocol Deviation Form and reported to the Sponsor.

14.9 Termination of the Trial

The study terminates for each patient 10 years after surgery with the final visit. Reasons for an earlier termination can be found in sections 14.6 and 14.7.

In the case of early termination of the study the Investigators have to be informed by the Sponsor. The regulatory authority(ies) and ethic committee(s) shall also be informed according to local and national regulations including the reason for termination.

15 Quality Control and Quality Assurance

The study is conducted in accordance with the Declaration of Helsinki [44] and the ISO 14155 Standard for the Clinical Investigation of Medical Devices part 1 and 2 [1;2].

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.

Moreover, local national authorities could audit the sites as well. In this particular case, all documents requested by the auditor(s) have to be available and handed out.

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 International 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.

16 Ethics and Regulatory

16.1 Standards

The study is conducted in accordance with the Declaration of Helsinki [44] and the ISO 14155 Standard for the Clinical Investigation of Medical Devices part 1 and 2 [1;2].

16.2 Ethics Committee Approval

Each Investigator will be responsible for obtaining national and/or local ethics committee approval (if appropriate) prior to conducting the research. Copies of Research Ethic Committee approval must be provided to Zimmer International Clinical Affairs to be retained on file. In circumstances where no ethics approval is required a signed letter to this effect should be provided to Zimmer International Clinical Affairs.

The Ethics Committee that approved the clinical investigation plan must be notified by the Investigator of any device related/possibly device related serious adverse events that occur during the course of the study and also of any clinical investigation plan amendments. The Ethics Committee must also be provided with a copy of the final clinical report, if applicable.

16.3 Patient Information and Consent

Prior to the treatment of the patients the Investigator will provide explanation about the study in detail, handout the Patient Information Form and the Patient Consent Form (see Appendix C). He will also be available for any question the patient has about the study. Further he will explain alternative treatment methods and that the patient’s data will be protected.

Finally a written consent of the patient will be obtained prior to surgery by signing the Patient Consent Form. The permission for the use of patient data for medical and scientific purposes is given as part of the Patient Consent Form.

16.4 Indemnity

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.

17 Amendment to Clinical Investigation Plan

All amendments shall be agreed with the Sponsor and the Investigator(s) and be recorded with a justification for the amendment. Approval of the Ethics Committee that reviewed the original Clinical Investigation Plan must be obtained if required according to the corresponding regulations.

18 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 an appropriate time period.

Pooled data may be used for training and meetings.

19 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 [44] and the ISO 14155 standard [1;2].

Clinical Study Manager (Name/ Date/ Signature)

François Geiger, CRA		

Quality Assurance (Name/ Date/ Signature)

Hassan Achakri, Director Int. Clinical Affairs		

The Declaration of Consent of each participating Investigator can be found in Appendix D.

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Appendix A List of Investigators

	Name	Professional Position	Name and Address of Institution
Principal Investigator	Dr. Ambrosius Müller	Leitender Arzt	Klinik für Orthopädie Kliniken Dr. Erler gGmbH, Nürnberg, Deutschland
Further Investigators	Prof. Reinhard Windhager	Leitung der Universitätsklinik für Orthopädie	Medizinische Universität Wien, Österreich
	Dr. Chaled El Masry	Facharzt für Orthopädie und Unfallchirurgie	Klinik Vincentinum, Augsburg, Deutschland
	Prof. François Gouin	Chief of the Department of orthopaedic and trauma surgery	Centre Hospitalier Universitaire, Nantes, France
	Dr. Jose Senaris	Head of the Department of Traumatology and Orthopaedic Surgery	Hospital Clinico Universitario de Santiago de Compostela, Spain

Appendix B Case Report Forms (CRF)

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Allofit IT Bearing System

Inclusion/Exclusion Criteria

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 1A

FOR ZIMMER USE ONLY

Patient Initials ☐☐☐

Case ID ☐☐☐☐☐☐

Date of Birth ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐

Operative Side ☐ Left ☐ Right

Visit Date ☐☐ - ☐☐ - ☐☐☐☐

1. Date Patient Informed Consent Obtained: Consent Date ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

2. Inclusion Criteria:

After the patient has signed the Ethics Committee approved informed consent, the patient must meet the following Inclusion/Exclusion criteria to participate in the clinical study.

Yes	No	
☐	☐	A. Patient is 18-75 years of age, inclusive.
☐	☐	B. Patient is skeletally mature.
☐	☐	C. Patient qualifies for primary unilateral or bilateral total hip arthroplasty (THA) based on physical exam and medical history including the following: (Check at least one and all that apply) ☐ Avascular necrosis (AVN) ☐ Osteoarthritis ☐ Inflammatory arthritis (e.g. rheumatoid arthritis) ☐ Post-traumatic arthritis
☐	☐	D. Patient has no history of previous prosthetic replacement device (any type, including surface replacement arthroplasty, endoprosthesis, etc.) of the affected hip joint(s).
☐	☐	E. Patient has a Harris Hip Score < 70 in the affected hip.
☐	☐	F. Patient is willing and able to provide written informed consent.
☐	☐	G. Patient is willing and able to cooperate in the required post-operative therapy.
☐	☐	H. Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent.
☐	☐	I. Patient has participated in the Informed Consent process and has signed the Ethics Committee approved informed consent.

If any response under Question 2, Inclusion Criteria is No, then patient is not eligible for study.

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Allofit IT Bearing System

Inclusion/Exclusion Criteria

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 1B

Patient Initials ☐☐☐

Case ID ☐☐☐☐☐☐

Date of Birth ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐

Operative Side ☐ Left ☐ Right

Visit Date ☐☐ - ☐☐ - ☐☐☐☐

3. Exclusion Criteria:

Yes	No	
☐	☐	A. The patient is: (Check all that apply) ☐ A prisoner ☐ Mentally incompetent or unable to understand what participation in the study entails. ☐ A known alcohol or drug abuser ☐ Anticipated to be non-compliant
☐	☐	B. The patient has a neuromuscular disorder, vascular disorder or other condition that could contribute to prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
☐	☐	C. The patient has a vascular (large and small vessel disease) insufficiency.
☐	☐	D. The patient has a neurologic condition in the ipsilateral or contralateral limb which affects lower limb function.
☐	☐	E. The patient has a diagnosed systemic disease that could affect his/her safety or the study outcome.
☐	☐	F. The patient is known to be pregnant.
☐	☐	G. The patient is unwilling or unable to give informed consent or to comply with the follow-up program.
☐	☐	H. The patient has received an investigational drug or device within the previous 6 months.
☐	☐	I. The patient has an active or latent infection in or about the affected hip joint or an infection distant from the hip joint that may spread to the hip hematogenously.
☐	☐	J. The patient has insufficient bone stock to fix the component. Insufficient bone stock exists in the presence of metabolic bone disease (i.e. osteoporosis), cancer, and radiation. NOTE: Dual Energy X-ray Absorptiometry (DEXA) may be used to assess the presence of adequate bone stock.
☐	☐	K. The patient has osteoradionecrosis of the operative hip.
☐	☐	L. The patient has a known sensitivity or allergic reaction to one or more of the implanted materials.
☐	☐	M. The patient has local bone tumors in the operative hip.
☐	☐	N. The patient is Grade III obese with a Body Mass Index > 40.

If any response under Question 3, Exclusion Criteria is Yes, then patient is not eligible for study.

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Allofit IT Bearing System

Demographic Evaluation

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 2

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Investigator ID

Operative Side ☐ Left ☐ Right

Date of Birth – – (DD-MM-YYYY)

Scheduled Date of Surgery – – (DD-MM-YYYY)

Visit Date – –

1. Patient Gender: ☐ Male ☐ Female

2. Patient Height: ☐ cm ☐ inches

3. Patient Weight: ☐ kg ☐ lbs

4. Primary Diagnosis: (Choose only one)

☐ Avascular Necrosis ☐ Post-traumatic Arthritis

☐ Osteoarthritis ☐ Other, specify:

☐ Inflammatory Arthritis (e.g. rheumatoid arthritis)

5. Prior Hip Operations: ☐ Yes* ☐ No

*If Yes, specify all that apply.

Contralateral	Ipsilateral	
☐**	Excl.	Femoral Osteosynthesis
☐**	Excl.	Acetabular Osteosynthesis
☐	☐	Femoral Osteotomy
☐	☐	Acetabular Osteotomy
☐	☐	Core Decompression
☐**	Excl.	Hip Resurfacing
☐**	Excl.	Endoprosthesis
☐**	Excl.	Total Hip Replacement
☐	☐	Other, specify below:

**If bilateral subject, must not be checked.

Contralateral Other: _____

Ipsilateral Other: _____

6. Significant Medical/Surgical History: ☐ Yes* ☐ No

*If Yes, check all that apply and then specify.

☐ Cardiovascular _____

☐ Dermatological _____

☐ Endocrine _____

☐ Gastrointestinal _____

☐ Genitourinary _____

☐ Hematologic _____

☐ Hepatic _____

☐ Musculoskeletal _____

_____

☐ Neurological _____

☐ Oncological _____

☐ Respiratory _____

☐ Renal _____

☐ Other, specify: _____

7. Current tobacco use? ☐ Yes* ☐ No

*If Yes, then specify:

☐ Daily ☐ Weekly ☐ Monthly

Describe: _____

8. Current alcohol use? ☐ Yes* ☐ No

*If Yes, then specify:

☐ Daily ☐ Weekly ☐ Monthly

Describe: _____

Initials of Person Completing Form:

10-JAN-2011

32126

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Allofit IT Bearing System

Operative Information

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 3A

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Study ID –

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

1. Surgical Approach: (Choose only one)

☐ Posterior ☐ Direct Lateral

☐ Anterior ☐ Anterior Lateral

☐ Posterior-Lateral ☐ Other, specify:

2. Anesthesia: (Mark all that apply)

☐ General ☐ Other, specify:

3. OR Time (Skin to Skin): minutes

Source = ☐ Anesthesia Record
☐ Circulating Nurse's Record

4. Estimated Blood Loss: cc

Source = ☐ Anesthesia Record
☐ Circulating Nurse's Record

5. Blood Replacement Products Used? ☐ Yes* ☐ No

*If Yes, specify:

☐ PRBC (Packed Red Blood Cell) Units

☐ Whole Blood Units

☐ Autologous Re-infusion Blood cc

☐ Other, please specify:

6. Was the capsule repaired? ☐ Yes* ☐ No

*If Yes, specify:

7. Acetabular Cup Information:

a. Catalog Number:

b. Lot Number:

c. How many mm of press fit? mm

8. Acetabular Liner Information:

a. Catalog Number:

b. Lot Number:

9. Femoral Head Component Information:

a. Catalog Number:

b. Lot Number:

10. Femoral Stem Component Information:

a. Catalog Number:

b. Lot Number:

c. How many mm of press fit? mm

31-AUG-2010

Initials of Person Completing Form:

54662

Zimmer

Allofit IT Bearing System

Operative Information

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 3B

Patient Initials

Case ID

Study ID –

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

11. Screw Fixation: ☐ Yes* ☐ No**

*If Yes, how many screws were implanted?

*If Yes, were remaining screw holes plugged? ☐ Yes ☐ No

**If No, were all of the screw holes plugged? ☐ Yes ☐ No

SCREW #1: a. Catalog Number:

b. Lot Number:

SCREW #2: a. Catalog Number:

b. Lot Number:

SCREW #3: a. Catalog Number:

b. Lot Number:

SCREW #4: a. Catalog Number:

b. Lot Number:

SCREW #5: a. Catalog Number:

b. Lot Number:

12. Was the Dome Hole plugged? ☐ Yes ☐ No

13. Were there any intraoperative complications? ☐ Yes* ☐ No

*If Yes, please complete Adverse Event form.

31-AUG-2010

Initials of Person Completing Form:

54662

zimmer

Allofit IT Bearing System

Immediate Postoperative Evaluation

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 4

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

1. Hospital Admission Date:

– – (DD-MM-YYYY)

2. Hospital Discharge Date:

– – (DD-MM-YYYY)

3. Was post-discharge physical therapy prescribed? ☐ Yes* ☐ No

*If Yes, then specify:

☐ Inpatient

☐ Skilled Nursing Facility

☐ Rehabilitation Center

☐ Outpatient

☐ Home Exercise

☐ Other, specify: _____

4. Postoperative DVT Prophylaxis Prescribed:

☐ Yes* ☐ No

*If Yes, specify all that apply:

Treatment	Duration
☐ Aspirin (Acetylsalicyclic acid)	days
☐ Warfarin (i.e. Coumadin)	days
☐ LMW Heparin	days
☐ Compression Stockings/TEDS	days
☐ Foot Pump/Sequential Compression Device	days
☐ Other, specify: _____	days

5. Heterotopic Ossification Prevention:

☐ None ☐ Radiation

☐ NSAID ☐ Other, specify: _____

6. Full Weight Bearing Ordered AFTER: days

7. Were there any postoperative complications?

☐ Yes* ☐ No

*If Yes, please complete Adverse Event form.

Comments:

31-AUG-2010

Initials of Person Completing Form:

26417

zimmer

Allofit IT Bearing System

Physical Exam

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 5

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Visit Date

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

1. **Patient Weight:** ☐ kg ☐ lbs

2. **Leg Length Discrepancy:** ☐ Legs Equal ☐ Right Short ☐ Left Short

   If Right Short or Left Short, specify: . ☐ cm ☐ inches

3. **Trendelenburg:** ☐ Positive ☐ Negative ☐ Unable to Test

4. **Charnley Classification:**

   ☐ Unilateral Joint, No Other Disability

   ☐ Bilateral Joint, No Other Disability

   ☐ Unilateral or Bilateral, with Other Joints or Medical Conditions Affecting Function

POST-OPERATIVE ONLY

5. **Have any Adverse Events occurred since last evaluation?** ☐ Yes* ☐ No

   *If yes, please complete Adverse Event Report.

Initials of Person Completing Form:

31-AUG-2010

60820

zimmer

Allofit IT Bearing System

Oxford Hip Score Form

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 17

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

DURING THE PAST FOUR WEEKS:

1. How would you describe the pain you usually had from your hip?

☐ None ☐ Very Mild ☐ Mild ☐ Moderate ☐ Severe

2. Have you had any trouble with washing and drying yourself (all over) because of your hip?

☐ No trouble at all ☐ Very little trouble ☐ Moderate trouble ☐ Extreme difficulty ☐ Impossible to do

3. Have you had any trouble getting in and out of a car or using public transport because of your hip? (whichever you tend to use)

☐ No trouble at all ☐ Very little trouble ☐ Moderate trouble ☐ Extreme difficulty ☐ Impossible to do

4. Have you been able to put on a pair of socks, stockings or tights?

☐ Yes, easily ☐ With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐ No, impossible

5. Could you do the household shopping on your own?

☐ Yes, easily ☐ With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐ No, impossible

6. For how long have you been able to walk before the pain from your hip became severe? (with or without a stick)

☐ No pain/>30 mins ☐ 16 - 30 mins ☐ 5 - 15 mins ☐ Around the house only ☐ Not at all

7. Have you been able to climb a flight of stairs?

☐ Yes, easily ☐ With little difficulty ☐ With moderate difficulty ☐ With extreme difficulty ☐ No, impossible

8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

☐ Not at all ☐ Slightly painful ☐ Moderately painful ☐ Very painful ☐ Unbearable

9. Have you been limping when walking, because of your hip?

☐ Rarely/never ☐ Sometimes or just at first ☐ Often, not just at first ☐ Most of the time ☐ All of the time

10. Have you had a sudden, severe pain - shooting/stabbing/spasms - from the affected hip?

☐ No days ☐ Only 1 or 2 days ☐ Some days ☐ Most days ☐ Everyday

11. How much has the pain from your hip interfered with your usual work (including housework)?

☐ Not at all ☐ A little bit ☐ Moderately ☐ Greatly ☐ Totally

12. Have you been troubled by pain from your hip in bed at night?

☐ No nights ☐ Only 1 or 2 nights ☐ Some nights ☐ Most nights ☐ Every night

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Allofit IT Bearing System

Patient Activity Questionnaire

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 7

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery ___ - ___ - ____ (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Visit Date ___ - ___ - ____

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

1. What is your activity level? (Choose one answer)

☐ Wholly inactive: dependent on others; cannot leave residence

☐ Mostly inactive: very restricted to minimum activities of daily living

☐ Sometimes participates in mild activities such as walking, limited housework and limited shopping

☐ Regularly participates in mild activities

☐ Sometimes participates in moderate activities such as swimming and can do unlimited housework or shopping

☐ Regularly participates in moderate activities

☐ Regularly participates in active events such as bicycling

☐ Regularly participates in very active events such as bowling or golf

☐ Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking

☐ Regularly participates in impact sports

POSTOPERATIVE PATIENTS ONLY

2. Are you satisfied with the results of your operation? ☐ Yes ☐ No

3. What is the status of your hip compared with your last visit? ☐ Better ☐ Worse ☐ Same

10-JAN-2011

Initials of Person Completing Form:

33665

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Allofit IT Bearing System

EQ-5D (EuroQol)

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 8

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

INSTRUCTIONS: Please indicate which statement best describes your own health state today. Do not tick more than one box in each group.

1. Mobility:

- ☐ I have no problems in walking about
- ☐ I have some problems in walking about
- ☐ I am confined to bed

2. Self-Care:

- ☐ I have no problems with self care
- ☐ I have some problems washing and dressing myself
- ☐ I am unable to wash or dress myself

3. Usual Activities (e.g. work, study, housework, family or leisure activities):

- ☐ I have no problems with performing my usual activities
- ☐ I have some problems with performing my usual activities
- ☐ I am unable to perform my usual activities

4. Pain/Discomfort:

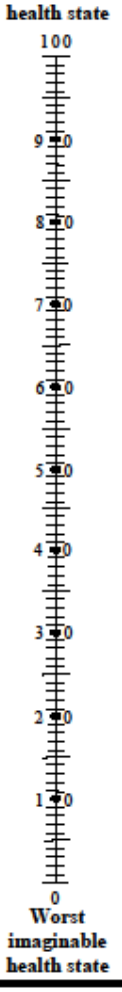
- ☐ I have no pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have extreme pain or discomfort

5. Anxiety/Depression:

- ☐ I am not anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am extremely anxious or depressed

6. Health State:

To help people say how good or bad a health state is, we have drawn a scale at the right (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked by 0. Please mark through the line at the place which indicates how good or bad your health state is today.



Office Use Only .

31-AUG-2010

Initials of Person Completing Form:

60363

zimmer

Allofit IT Bearing System

Harris Hip

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 9

FOR ZIMMER USE ONLY

Patient Initials ☐☐☐

Case ID ☐☐☐☐☐☐

Date of Surgery ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐

Operative Side ☐ Left ☐ Right

Visit Date ☐☐ - ☐☐ - ☐☐☐☐

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

1. Evaluation of pain: (check one box only)

☐ None ☐ Moderate
☐ Slight ☐ Marked
☐ Mild ☐ Disabled

2. Evaluation of function:

A. Daily Activities (check one box in each subsection):

1. Stairs:
   - ☐ Normally without use of banister/railing
   - ☐ Normally using banister/railing
   - ☐ Using any method
   - ☐ Unable to do stairs
2. Transportation
   - ☐ Able to enter public transportation
   - ☐ Unable to enter public transportation
3. Sitting:
   - ☐ Comfortable in any chair for one hour
   - ☐ Comfortably on a high chair for one-half hour
   - ☐ Unable to sit comfortably in any chair
4. Socks and Shoes:
   - ☐ Puts on socks and shoes with ease
   - ☐ Puts on socks and shoes with difficulty
   - ☐ Unable to put on socks and shoes

B. Gait (Check one box in each subsection):

1. Limp
   - ☐ None
   - ☐ Slight- detected by trained observer
   - ☐ Moderate - detected by patient
   - ☐ Severe - markedly slows or alters gait
2. Support
   - ☐ None
   - ☐ Single cane for long walks
   - ☐ Single cane most of the time
   - ☐ One crutch
   - ☐ Two canes
   - ☐ Two crutches (walker)
   - ☐ Unable to walk even with support
3. Distance walked
   - ☐ Unlimited
   - ☐ Six blocks (> 500 m, 31-60 min)
   - ☐ Two or three blocks (< 500 m, 2-30 min)
   - ☐ Indoors only
   - ☐ Bed and chair

3. Absence of deformity: (check one box in each subsection)

A. $\geq$ 30° fixed flexion contracture:
☐ Absence ☐ Presence

B. $\geq$ 10° fixed adduction:
☐ Absence ☐ Presence

C. $\geq$ 10° fixed internal rotation in extension:
☐ Absence ☐ Presence

D. Limb-length discrepancy > 3.2 cm:
☐ Absence ☐ Presence

4. Range of Motion:

A. Flexion: ☐☐☐°

B. Abduction (In Flexion) ☐☐☐°

C. Adduction (In Flexion) ☐☐☐°

D. External Rotation (In Extension) ☐☐☐°

E. Internal Rotation (In Extension) ☐☐☐°

Initials of Person Completing Form: ☐☐☐

31-AUG-2010

17635

Zimmer
Allofit IT Bearing System

Concomitant Medication(s) Form

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 10

FOR ZIMMER USE ONLY

Patient Initials ☐☐☐ Case ID ☐☐☐☐☐☐ Date of Surgery ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐ Operative Side ☐ Left ☐ Right Visit Date ☐☐ - ☐☐ - ☐☐☐☐

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

1. Has patient taken any pain, antibiotic, or anticoagulant medication since the last study evaluation?
☐ Yes* ☐ No *If Yes, complete the table below.

Medication Type (See descriptions below)	Medication Name	Frequency	Duration (if known) (DD-MM-YYYY)
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing
☐ Pain ☐ Antibiotic ☐ Anticoagulant		☐ Daily ☐ Weekly ☐ PRN	Start Date __-__-____ End Date __-__-____ ☐ Continuing

Initials of Person Completing Form: ☐☐☐

31-AUG-2010 39138

zimmer

Allofit IT Bearing System

Radiographic Evaluation 1

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 11A

FOR ZIMMER USE ONLY

Patient Initials ☐☐☐ Case ID ☐☐☐☐☐☐ Date of Surgery ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐ Operative Side ☐ Left ☐ Right Date of X-ray ☐☐ - ☐☐ - ☐☐☐☐

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

Acetabular Side - A/P View:

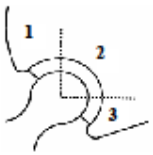
1. **Inclination of Cup (angle):** ☐☐°

2. **Version of Cup:** ☐ Neutral ☐ Anteverted ☐☐° ☐ Retroverted ☐☐°

3. **Cup Migration?** ☐ Yes* ☐ No
   *If Yes, specify: ☐☐.☐ mm Direction: ☐ Superior ☐ Medial

4. **Radiolucency (mm):**

		Zone 1	Zone 2	Zone 3
a. Prosthesis/Bone Interface:	☐ None	☐☐.☐	☐☐.☐	☐☐.☐
b. Progressive Radiolucency:	☐ None	☐☐.☐	☐☐.☐	☐☐.☐
5. Condensation of Bone:	☐ None	☐☐.☐	☐☐.☐	☐☐.☐
6. Osteolysis:	☐ None	☐☐.☐	☐☐.☐	☐☐.☐



7. **Acetabular Screws:**
   a. Screw Breakage: ☐ Yes ☐ No ☐ N/A
   b. Screw Radiolucency: ☐ Yes ☐ No ☐ N/A
   c. Sclerotic Line: ☐ Yes ☐ No ☐ N/A

8. **Comments:**

07-JAN-2011

Initials of Person Completing Form: ☐☐☐

14034

zimmer

Allofit IT Bearing System

Radiographic Evaluation 2

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 11B

FOR ZIMMER USE ONLY

Patient Initials ☐☐☐ Case ID ☐☐☐☐☐☐ Date of Surgery ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID ☐☐☐☐ Operative Side ☐ Left ☐ Right Date of X-ray ☐☐ - ☐☐ - ☐☐☐☐

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

Femoral Side

1. **Stem Position:** ☐ Varus ☐ Valgus ☐ Neutral
2. **Stem Subsidence:** ☐ Yes* ☐ No
   *If Yes, specify: ☐☐.☐ mm
3. **Stem Shift:** ☐ Yes* ☐ No
   *If Yes, specify: ☐☐.☐ mm Direction: ☐ Varus ☐ Valgus

A/P View:

4. **Radiolucency (mm):**

	None	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7
a. Prosthesis/Bone Interface:	☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐
b. Progressive Radiolucency:	☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐

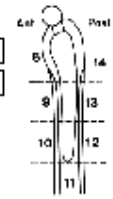
5. **Osteolysis (mm):** ☐ ☐☐.☐ ☐☐.☐ ☐☐.☐ ☐☐.☐ ☐☐.☐ ☐☐.☐ ☐☐.☐

Lateral View:

6. **Radiolucency (mm):**

	None	Zone 8	Zone 9	Zone 10	Zone11	Zone 12	Zone 13	Zone 14
a. Prosthesis/Bone Interface:	☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐
b. Progressive Radiolucency:	☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐	☐☐.☐

7. **Osteolysis (mm):** ☐
8. **Calcar Rounding:** ☐ Yes ☐ No
9. **Calcar Resorption:** ☐ Yes* ☐ No *If Yes, specify amount: ☐☐.☐ mm
10. **Lateral Stem Position:** ☐ Anterior ☐ Posterior ☐ Neutral



Other Significant Findings:

1. **Heterotopic Ossification?** ☐ Yes* ☐ No
   If Yes, specify:

Location	Class (see grading key)				
Medial Inferior	☐ None	☐ I	☐ II	☐ III	☐ IV
Lateral Superior	☐ None	☐ I	☐ II	☐ III	☐ IV

KEY: Brooker Heterotopic Ossification Grading

Class I = Islands of bone
Class II = Bone Spurs, Gap > 1 cm
Class III = Bone Spurs, Gap < 1 cm
Class IV = Bone Ankylosis

2. **Are any other abnormalities observed?** (i.e. sclerotic lines or radiodense lines suggesting bone/tissue ingrowth may not be occurring)
   ☐ Yes* ☐ No
   If Yes, specify: _____

07-JAN-2011

Initials of Person Completing Form: ☐☐☐

17618

zimmer

Allofit IT Bearing System

Adverse Event Report

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 12

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

1. **Complication Code (see descriptions at right):**

2. **Details of Event:**

3. **Side:** ☐ Left ☐ Right ☐ N/A

4. **Date of Onset:** – – (DD-MM-YYYY)

5. **Type of Event:** ☐ AE ☐ SAE ☐ ADE ☐ SADE

6. **Severity:** ☐ Mild ☐ Moderate ☐ Severe

7. **Relation to Device:** ☐ Not Related ☐ Uncertain ☐ Probably ☐ Definitely

8. **Details of Treatment:**

9. **Outcome:**

☐ Resolved - Date: – – (DD-MM-YYYY)

☐ Tolerated

☐ Pending

☐ Study Withdrawal - Date: – – (DD-MM-YYYY)

☐ Device Removal/Reoperation - Date: – – (DD-MM-YYYY)

☐ Death - Date: – – (DD-MM-YYYY)

General Complications

01 Cardiovascular
02 Dermatological
03 Endocrine
04 ENT
05 Gastrointestinal
06 Genitourinary / Renal
07 Hematological
08 Infection (non-hip)
09 Musculoskeletal (non-hip)
10 Neurological
11 Oncological
12 Pulmonary/Respiratory

88 Other General Complication

Hip Related Complications

40 Acetabular Implant Failure
41 Acetabular Implant Fracture
42 Acetabular Implant Loosening
43 Deep Vein Thrombosis
44 Delayed Wound Healing
45 Dislocation
46 Femoral Implant Failure
47 Femoral Implant Fracture
48 Femoral Implant Loosening
49 Fracture of Acetabulum
50 Fracture of Femur
51 Fracture of Trochanter
52 Hematoma
53 Heterotopic Ossification
54 Infection (hip), superficial
55 Infection (hip) deep
56 Instability
57 Nerve Injury/Palsy
58 Stem Subsidence
59 Subluxation
60 Thigh/Groin/Hip Pain
61 Trochanteric Bursitis
62 Vascular Deficit

98 Other Hip Related Radiographic Finding
99 Other Hip Related Complication

10. **Date Reported to Ethics Committee:** – – (DD-MM-YYYY) ☐ Not Required ☐ Future Report

Initials of Person Completing Form:

16162

31-AUG-2010

zimmer

Allofit IT Bearing System

Protocol Deviation

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 13

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date ☐☐ - ☐☐ - ☐☐☐☐

Examination Period: ☐ Preop ☐ 6 Month ☐ 1 Year ☐ 2 Year ☐ 3 Year ☐ 5 Year ☐ 7 Year ☐ 10 Year

1. Type of Deviation:

- ☐ Informed Consent
- ☐ Inclusion/Exclusion
- ☐ Surgical Procedure
- ☐ Missed Visit
- ☐ Visit Outside Protocol Window
- ☐ Missed X-rays, specify:
  - ☐ A/P
  - ☐ Lateral
- ☐ Incomplete CRFs, specify: _____
- ☐ Other, specify: _____

2. Explanation of Protocol Deviation:

3. Date Deviation Occurred: ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

If missed visit, date is the last day of the protocol allowed window.

4. Date Deviation Reported to Zimmer: ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY)

5. Action Required:

6. Does your Ethics Committee require this Protocol Deviation be reported? ☐ Yes* ☐ No

*If Yes, date deviation reported to Ethics Committee : ☐☐ - ☐☐ - ☐☐☐☐ (DD-MM-YYYY) ☐ Future report

Initials of Person Completing Form: ☐☐☐

31-AUG-2010

43732

zimmer

Allofit IT Bearing System

Study Completion

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 14

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

1. **Date of Study Completion:** – – (DD-MM-YYYY)

2. **Date of Last Assessment:** – – (DD-MM-YYYY)

3. **Study Completion Status:**

☐ Patient Completed Study According to Protocol

☐ Subject Requested Discontinuation

Reason: _____

☐ Implant Removal

If device removed, complete Adverse Event Report and Explanted Device Form.

☐ Subject Expired

Date: – – (DD-MM-YYYY)

Cause: _____

☐ Other, specify: _____

☐ Lost to Follow-Up

Reason: _____

Dates of Attempted Contact (DD-MM-YYYY)	Method
– –	_____
– –	_____
– –	_____
– –	_____

4. **Additional Comments:**

31-AUG-2010

Initials of Person Completing Form:

45002

zimmer

Allofit IT Bearing System

Explanted Device Form

PLEASE COMPLETE ONE FORM PER OPERATIVE SIDE

Form 15

FOR ZIMMER USE ONLY

Patient Initials

Case ID

Date of Surgery – – (DD-MM-YYYY)

Investigator ID

Operative Side ☐ Left ☐ Right

Form Completion Date – –

1. **Date of Explantation:** – – (DD-MM-YYYY)

2. **Components Removed:** (check all that apply)
   - ☐ Acetabular Cup
   - ☐ Acetabular Liner
   - ☐ Acetabular Screws
   - ☐ Femoral Head
   - ☐ Femoral Stem

3. **Reason for Revision:** (check all that apply)

   ☐ Implant Failure ☐ Instability ☐ Infection ☐ Other, specify: _____

   If Implant Failure, specify:
   - ☐ Acetabular Cup
   - ☐ Acetabular Liner
   - ☐ Acetabular Screws
   - ☐ Femoral Head
   - ☐ Femoral Stem

4. **Implant Damage Due to Removal?** ☐ Yes* ☐ No

   *If Yes, specify: _____

5. **Mechanical wear damage believed to have occurred *in-vivo*?** ☐ Yes* ☐ No

   *If Yes, specify: _____

6. **Disposition of device(s):**

   ☐ Zimmer Date: – – (DD-MM-YYYY)

   ☐ Other Date: – – (DD-MM-YYYY)

7. **Has your Ethics Committee been notified?** ☐ Yes* ☐ No ☐ Not Required

   *If Yes, specify date: – – (DD-MM-YYYY)

Note: Please complete Adverse Event Report and Study Completion form.

Comments:

31-AUG-2010

Initials of Person Completing Form:

8330

Appendix C Patient Information and Patient Consent

Allofit® IT with HXPE in Total Hip Arthroplasty
A multi-center, prospective, non-controlled post market surveillance study

PATIENT INFORMATION

Dear patient,

You are currently being treated for a degenerative disease or trauma of your hip. The conservative treatments have failed and therefore your surgeon has recommended the implantation of a Zimmer total hip replacement system. In this regard you are being invited to take part in a study (sometimes called a Clinical Investigation). Before you decide to participate, it is important for you to understand why the study is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your general practitioner/health care professional if you wish. Ask your surgeon if there is anything that is not clear or if you would like to receive more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

This study will investigate how well the patients are doing after their treatment with the Zimmer total hip replacement system that you will receive, the *Allofit* IT HXPE Bearing System. This will be performed by taking radiographs, and by asking you to complete some questionnaires concerning your health/well-being and pain before your surgery and at the follow-up - examinations. The anonymized patient data from different study centres is then being collected and evaluated in up to 200 patients. This information is very important for the surgeons as well as the manufacturer of the implant, as it provides the scientific basis for a continuous improvement in the treatment of patients with degenerative diseases or trauma of the hip. This information may be used for future product market approvals as well.

What is a total hip replacement system?

Hip joints can become damaged by disease, such as arthritis and this causes the hip to be very painful and difficult to move. If other treatments (such as steroids or pain-relieving drugs) do not help, the patient can undergo hip replacement surgery. This involves an operation. An orthopaedic surgeon replaces the hip joint by removing the diseased parts of the joint and inserting an artificial hip joint (prosthesis) made of metal. The total hip replacement system you will receive is sometimes used in active or younger patients. It was developed according to the latest scientific knowledge by leading surgeons together with the company Zimmer.

Description of the device

The *Allofit* IT Acetabular System is composed of three components: a femoral (thighbone) component with femoral head, an acetabular shell (hip socket) component, and an acetabular liner component which fits inside the acetabular shell component. All system components are CE marked and commercially available.

Allofit IT Acetabular Shell

The acetabular shell is made from Titanium (Protasul®-Ti Alloy). This component replaces the damaged surface of the hip socket. Screws may be used to secure the shell in your hip socket if necessary.

Longevity® Liner

The Longevity Liner is made from highly cross-linked Polyethylene and is secured in the acetabular shell by a snap feature.

What other types of treatment are available?

A hip operation is normally carried out when no other treatments are available. For example, a surgeon may suggest that a patient undergo hip surgery when the patient no longer benefits from steroid injections and/or pain-relieving drugs. There are a few surgical procedures, other than the hip replacement, that may offer benefit to some patients, although this is very dependent on how damaged the hip is. If you require more information, please discuss the alternatives with your surgeon.

What happens in this clinical study?

The participation in this study does not change anything in the care or after-care you would normally receive when having the surgery. Before your surgery, your surgeon will examine you. This will involve measuring how much you can move your legs and asking you how much pain you feel during certain activities. Standard radiological images will be taken. You will then undergo surgery, which involves a general anesthesia. During surgery, your hip will be opened up, the diseased parts of your joint removed and then the artificial hip implanted. After the operation, you may receive physiotherapy to help the healing process. You will be asked to visit the surgeon at 6 months, 1, 2, 3, 5, 7, and 10 years after your surgery. Each time, you will be asked to complete a set of questionnaires. Questions will include how much pain you feel, how much movement you have in your hips, your current quality of life, and radiological images of your hip joint will also be taken. This data will be used to provide an indication of how successful your surgery has been.

Who can you contact if you have questions regarding the study?

If you have questions regarding the study, please feel free to contact the following surgeon any time: (Surgeon Name, Phone +xxxx).

Potential Benefits and Risks

Many people have received a hip replacement surgery. After surgery, they have found they suffer from much less pain and can move their hip more easily. We hope your treatment will also be very successful, although this cannot be guaranteed. The information we get from documenting the outcome of your surgery will help us to measure the performance of this prosthesis and show that it can offer long-term benefit to many patients.

Any surgery involves a small risk – from the anesthesia and from the surgical procedure. The foreseeable risks and possible side effects associated with the surgical procedure will be explained to you by the surgeon. Furthermore, there is a possibility that the surgery may not give all the benefits we hope. The risks, however, are not greater than if you were undergoing the surgery without participating in this study. If you need any more information or to report a study related injury, please contact your surgeon. If an injury is caused to you as a result of procedures undertaken in accordance with the Study, Zimmer is liable for damages resulting from the Study.

How do you take part in the study?

You are free to decide whether you want to take part in this study. Refusal to participate will not result in any penalty or loss of benefits for which you are otherwise entitled. If you decide to participate, please sign the consent form that confirms you have read this leaflet and you agree to be part of the study. Clinical appointments will then be made to start the treatment.

If you consent to take part in this study, your medical records will remain confidential at all times, although relevant sections may be inspected by a qualified member of the International Clinical Affairs Department of Zimmer, the sponsoring company. This is necessary to verify that the study is being carried out correctly and the data collected is true and accurate. The data generated from this study will be stored by the Zimmer International Clinical Affairs Department on paper and electronically for up to 15 years after study termination. Access to this data will be limited to those directly involved in the running of the study and to the regulatory authorities. You will only be identified by your study identification number, date of birth, initials, sex and date of surgery. Your name will not be disclosed outside the hospital at any time. You have the right to see the information that Zimmer holds about you, please contact your surgeon if you wish to do so. The data generated from this study may be published in a scientific journal, but you will not be identified as an individual in any publication.

You can leave this study at any moment and for whatever reason. Furthermore, this will not have any detrimental effect on your subsequent treatment. The treatment will carry on as if you had never been part of the study. If any new significant findings become available during the study which could affect your willingness to continue participation, you will be notified.

PATIENT INFORMED CONSENT FORM

Study Title: *Allofit*® IT with HXPE in Total Hip Arthroplasty
A multi-center, prospective, non-controlled post market surveillance study

To be completed by the patient:

Have you read the information sheet about this study?	YES/NO
Have you been able to ask questions about this study?	YES/NO
Have you received answers to all your questions?	YES/NO
Have you received enough information about this study?	YES/NO

Which surgeon have you spoken to about this study?

Dr. / Mr. / Prof.……...

Do you understand that you are free to withdraw from this study?	YES/NO
At any time?	YES/NO
Without giving a reason for withdrawing?	YES/NO
Without affecting your future medical care?	YES/NO
Do you agree to take part in this study?	YES/NO
Are you involved in any other trials/studies?	YES/NO

How many? ☐

Do you give authorization for your data to be stored by Zimmer?	YES/NO

Signed:…….. Date:……

Name (Block Letters):…….

Surgeon:…….. Date:……

Name (Block Letters):…….

Appendix D Investigator's Consent to the Clinical Investigation Plan

Investigators Agreement

Allofit® IT with HXPE in Total Hip Arthroplasty

A multi-centre, prospective, non-controlled post market surveillance study

Clinical Investigation Plan ID CME2010-25H

I, as an Investigator, have read the Clinical Investigation Plan for this study and agree that it contains all the necessary details for me to carry out this study. I will conduct the study as outlined therein. This includes that I will follow the inclusion / exclusion criteria for appropriate patient selection for study participation.

I will, if necessary, provide Zimmer with a copy of the written approval from the Ethics Review Body. I will also make sure that all other applicable requirements for study conduction in my study centre are met.

I will aim to finalize patient recruitment at my study centre within 12 months after study start. I will also aim to record the data of all study subjects until the 10-years follow-up visit.

I will fill in the Case Report Forms provided by Zimmer for this clinical study and will provide them on a regular basis to Zimmer International Clinical Affairs for verification. Furthermore, I will answer all data related questions upon request.

I am aware that I am allowed to publish my results and that Zimmer shall have the right to review all manuscripts before submission. I am also aware that my data must not be published without having given my permission. However, Zimmer has the right to make use of the results obtained from this study for internal training and marketing purposes.

Herewith, the undersigned certifies that he/ she has read and examined the present protocol carefully and declares that he/ she is in agreement with the demands and conditions noted. He/ she hereby consent that he/ she will perform the study according to the requirements of the Declaration of Helsinki [44] and the ISO 14155 standard [1;2].

Investigator (Name/ Date/ Signature)
