## Study protocol

# An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision cup.

| | |
|---|---|
| **Short title:** | DELTA REVISION CUP |
| **Protocol ID:** | H-34 |
| **Date / Version:** | 28 September 2020 v. 1.1. |
| **Study devices:** | DELTA Revision acetabular cup |
| **Sponsor:** | LimaCorporate S.p.A.<br>Via Nazionale, 52<br>33038 Villanova di San Daniele<br>Udine, Italy |

**Study Protocol Approval Page**

This **Study Protocol H-34, Delta Revision cup, version 1.1 dated 28 September 2020** has been read and approved by:

Sponsor: Nicole Karen Esposito

Title: VP Global Marketing and Market Access, LimaCorporate S.p.A.

Signature:

Date: 02 Nov 2020

Principal Investigator: Dr. Jerzy Białecki

Title: Head of Orthopaedic Clinic Department CMKP

Signature:

Date: 10.11.2020

**Investigator's Statement and Signature**

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol; modifications to the study or protocol are acceptable only with a mutually agreed upon protocol amendment. I agree to await Ethics Committee approval for the protocol and informed consent before initiating the study, to obtain informed consent from subjects prior to their enrolment in the study, to collect and record data as required by this protocol and case report forms, to prepare the final and adverse effect reports as required by this protocol, and to maintain study documentation for the period of time required.

**Protocol H-34, Delta Revision cup, version 1.1 dated 28 September 2020**

| | |
|---|---|
| Jury Biafelli | 10.11.2020 |
| **Principal Investigator** | **Date** |

**Protocol Revision History**

| Protocol Amendment & Date | Brief description of Amendments | Brief justification of amendment |
|---|---|---|
| **v.1.1, 28.September.2020** | **Section 6.1: Delta Revision acetabular cup**<br>The indications in the section do not match the indications of the current Indication For Use (IFU) and study inclusion/exclusion criteria. For this reason, the following indications are been removed:<br>- non-inflammatory degenerative joint disease such as osteoarthritis, avascular ne-crosis;<br>- hip dislocation using protruded liners, spacers (which allow better protection, mul-tiple offset and soft tissue tensioning) and using coupling for dual mobility (which reduces jumping distance);<br>- rheumatoid arthritis;<br>- post-traumatic arthritis;<br>- correction of functional deformity in case of acetabulum verticalization, antever-sion and retroversion;<br>- fractures of femoral neck; | The indications in the section 6.1. do not match the indications of the current IFU and study inclusion/exclusion criteria. For this reason, the indications for primary surgery are been removed in order to reflect the patient population included in this study and the real practice of the sites. |
| | **Section 12.1 Compliance with laws and regulations:**<br>This study will be conducted in full conformance with the EN ISO 14155:2020 "Clinical investigation of medical devices for human subjects — Good clinical practice".<br><br>**Section 13.3 Monitoring procedures:**<br>The Sponsor is responsible for collecting these data and verifying that the study is conducted in compliance with the protocol, EN ISO 14155:2020 "Clinical investigation of medical devices for human subjects — Good clinical practice". | Sections 12.1 and 13.3 are been modified in order to reflect the new ISO 14155:2020 released in July 2020. |
| | The protocol version and protocol date have been revised from v.1.0 dated 04.February.2020 to v.1.1 dated 28.September.2020. | The protocol version and protocol date have been revised in order to reflect the changes made to the clinical investigation plan. |
| | The footnote has been modified from v.1.0 dated 04.February.2020 to v.1.1 dated 28.September.2020 | The footnote has been corrected to be consistent with the rest of the clinical investigational plan. |
| | The protocol synopsis has been updated to reflect the changes to the protocol, where applicable. | The protocol synopsis has been updated to reflect the changes to the protocol, where applicable. |

# TABLE OF CONTENTS

## LIST OF APPENDICES

## Protocol Synopsis

| | |
|---|---|
| **Study title** | An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup. |
| **Protocol ID** | H-34; 28 September 2020 v. 1.1 |
| **Objectives** | **Primary objectives**<br>- To assess the clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years<br>**Secondary objectives**<br>- To assess the radiographical and clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years<br>- To evaluate the safety profile of the DELTA Revision acetabular cup used in real life settings over a period of 5 years<br>- To describe baseline data (demographic data, primary diagnosis, aetiology, affected side, type of surgery and intra-operative data) of patients with Delta Revision acetabular cup |
| **Endpoints** | **Primary endpoints**:<br>The evaluation of Harris Hip Score (HHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant.<br><br>**Secondary endpoints:**<br>- Evaluation of Range of Motion (ROM) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant;<br>- Evaluation of Oxford Hip Score (OHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant;<br>- Survivorship of the implant (Kaplan-Meier estimate) at 2 years of follow-up after surgery;<br>- Radiographic implant evaluation and stability assessment of the DELTA Revision acetabular cup at the following timepoints: at discharge, 2 months, 6 months, 1 year, and 2 years after the implant<br>- Incidence, type and severity of all the Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Device Effects (ADEs) and Serious Adverse Device Effects (SADEs) at intraoperatively, discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant. |
| **Study type and design** | Post-market, open label, observational, prospective, longitudinal cohort study conducted in patients who have to perform a total hip arthroplasty with Delta Revision Acetabular Cup. |
| **Study duration** | Expected recruitment duration: 30 months. |

| | |
|---|---|
| | The study will be considered to have started when the first implant will be performed and ended when the last patient has completed the final study assessment visit or phone interview. |
| **Sample size** | Total enrollment assuming a 40% loss to follow-up is 29/0.60 ≈ 49 subjects.<br>An effective sample size of 29 subjects provides 90% power to demonstrate that the average change from baseline in the HHS is greater than 20 points assuming an observed average change of 32 points. |
| **Treatment** | Total hip arthroplasty with DELTA Revision acetabular cup.<br>This is an observational study designed to reflect real life clinical practice as closely as possible. Thus, clinicians are free to choose the method to implant and total hip arthroplasty in accordance with the current local Delta Revision acetabular cup Indication for Use and current clinical practice |
| **Study devices** | CE marked DELTA Revision acetabular cup. |
| **Study sites no.** | Expected number of study centres: 1<br>The number of centres may be revised, based on the recruitment rate.<br>Centres will be selected based on the number of patients who will receive total hip arthroplasty with DELTA Revision acetabular cup per year. |
| **Selection criteria** | **Inclusion criteria**<br>Patients must meet the following criteria for study entry:<br>1. Male or female.<br>2. Age ≥ 18 years old.<br>3. All patients must give written informed consent approved by the study site's Institutional Review Board (IRB)/Ethical Committee (EC).<br>4. Adult patients in whom a decision has already been made to perform a total hip arthroplasty with DELTA Revision acetabular cup as per indication for use. The decision to implant DELTA Revision acetabular cup must be taken prior to, and independently from the decision to enroll the patient. This decision should be made in accordance with routine clinical practice at the study site concerned.<br>5. Patient is able to comply with the protocol.<br><br>**Exclusion criteria**<br>A patient will not be included in the study if they meet any of the following criteria:<br>1. Adult patients with any DELTA Revision acetabular cup contraindication for use as reported in the current local Instruction for use.<br>2. For female patients, current pregnancy and/or lactation or planning a pregnancy. |
| **Time-points** | An Electronic Data Capture system will be used to collect data in electronic format. Data will be collected at the following time-points:<br>- **Pre-operative Visit** (Screening).<br>- **Intra-operative/Discharge visit** (Enrollment visit).<br>- **Follow-up (FU) visits** as per standard of care: 2 months, 6 months, 1 year, 2 years after surgery. |

| | |
|---|---|
| | - **Survival Follow-Up (SFU) visits:** yearly at longer follow-up to collect survivorship and safety data at Survival Follow-Up visit 3 years, 4 years and 5 years after the surgery. The Survival Follow-Up visit can be performed as telephone interview (if applicable according to the clinical practice). |
| **Study procedures** | Relevant data will be captured on an eCRF. These data which will be transmitted to the sponsor for analysis, will be anonymous and will be identified by a patient number. As this study is non-interventional, all the data collected will be in accordance with the practice of clinicians implanting DELTA Revision acetabular cup.<br>At pre-operative, intra-operative, discharge and each Follow-Up visit, the following information will be collected:<br>- Medical history and demographic data (only at pre-operative visit);<br>- Primary diagnosis and physical examination (only at pre-operative visit);<br>- Surgical data (only at intra-operative visit);<br>- X-rays as per standard care;<br>- Radiographic evaluation;<br>- Clinical assessment (HHS, ROM, OHS);<br>- Assessment the type, nature and severity of any DD, AE, ADE, SAE and SADE;<br>- Survivorship of implant.<br>For Survival Follow-Up visits:<br>- Assessment the type, nature and severity of any AE, ADE, SAE and SADE;<br>- Survivorship of the implant |

## LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

| | |
|---|---|
| **AE** | Adverse Event |
| **ADE** | Adverse Device Effect |
| **AP** | Antero-Posterior |
| **CCD** | Caput-Collum-Diaphyseal |
| **CRO** | Contract research organisation |
| **CSR** | clinical study report |
| **EC** | Ethical Committee |
| **ECRF** | Electronic case report form |
| **DD** | Device Deficiency |
| **HHS** | Haris Hip Score |
| **IFU** | Instructions for Use |
| **IRB** | Institutional Review Board |
| **LLG** | Leg Length Discrepancy |
| **OHS** | Oxford Hip Score |
| **PRO** | Patient-reported outcome |
| **PROM** | Patient-reported outcome measure |
| **ROM** | Range of motion |
| **SAE** | Serious Adverse Event |
| **SADE** | Serious Adverse Device Effect |
| **USADE** | unanticipated serious adverse device effect |
| **THA** | Total hip arthroplasty |

# 1 Background

## 1.1 Background on cementless acetabular cups

Cementless acetabular cup is designed for long-term implantation inside the human body and must be exclusively utilized by orthopaedic surgeons having a good knowledge of the specific operative technique.
The main goal of a hip joint prosthesis is to reproduce the articular anatomy reducing pain and give articular mobility to the patient. The degree of pain reduction and mobility depends in part on the pre-operative situation, intra-operative options and on the post-op rehabilitation.
Cementless acetabular cups have been designed between 1970 and 1980 to overcome the "cement disease", a progressive bone resorption related to particulate debris at the cement-bone interface that is considered the main cause of failure of cemented polyethylene (PE) cups due to aseptic loosening [1] [2]. Excluding the cement, primary stability of the acetabular component can still be achieved in different ways biomechanically, by threads or press-fit with or without screws.
Threaded components have been advocated because of their high primary stability which is a prerequisite factor for bone ingrowth and long-term fixation [3]. The primary stability of threaded implants is based on a press-fit situation by a thread being screwed into the bone, and depends on many factors such as the geometry of the cup, design of the threads or rims, implant material, and surface finishing, before bony integration happens [2].
An adequate primary stability is an essential condition for a good subsequent osteointegration and thus also for a long-term secondary stability [4]. The long-term success of threaded cups is also dependent upon the cup position that is greatly influenced by the screw-in behaviour of threaded cups, which is dependent on the thread shape [5].
All the above-mentioned concepts have been understood only with the second generation of cementless cups, which are composed by a metallic acetabular shell with a rough surface to improve osseous integration and therefore long-term survivorship [5]. In fact, the original design was intended with smooth surfaces since it was believed that the pure mechanical interlocking between the bone and the metal shell would provide adequate primary and long-lasting fixation. It soon became obvious that primary fixation only was not sufficient to ensure the longevity of this implant as the mid-term high rates of loosening were reported; hence biological fixation was considered necessary to achieve satisfactory long-term results. Complications reported for their first generation include early loosening, cup breakage and soft tissue damage [5].
The DELTA Revision acetabular cup was devised keeping all these objective facts in mind: primary fixation of the cup is obtained by press-fit, and by bone screws; secondary fixation and osseointegration of the system is guaranteed by a porous Titanium coating.
The caudal hook is intended to be useful also for intra-surgery guide for the restoring of the rotation centre, and it features an adequate conformation in order to avoid an excessive local constraint.

## 1.2 Study rationale

Delta Systems devices are used by surgeons to replace the acetabular cavity during hip surgery.

Delta system includes acetabular metal shells, liners and other accessories. The Delta system allows both the main fixation concepts, press-fit and screwing, therefore, by choosing the proper model, the implant can be adapted to the morphology and bone trophism of the patient.
Cups are characterized by a spherical shape and are fixed to the bone without the use of cement. Delta acetabular cups are intended to be coupled with Delta liners, spacers and hemispheric modules and are available in different materials. Delta Revision acetabular cup is the device object of this study, while liners and spacers, femoral heads, stems, hemispheric modules and bone screws are considered additional medical devices and accessories.
LimaCorporate develops and manufactures its products in close and continuous cooperation with orthopedic surgeons. The Delta System devices have been on the market for several years, are well established, and did not receive substantial design changes.
As required by MEDDEV 2.7/1 [Document 2], the market environment and clinical databases were searched to identify devices which demonstrated clinical, technical and biological equivalence to the Delta system.
Therefore, the equivalence was based on comparison with historic models of acetabular systems which are still nowadays considered state-of-the-art and are appreciated for their long-term clinical history of implantations.
There is sufficient clinical data on many Delta system models and thus comparison to an equivalent device was hereby focusing on Delta Revision acetabular cups.
However, data from report ad hoc from National Registries conducted by LimaCorporate are especially relevant to the design of the current trial and is summarized below.
Since 2000, the Register of Orthopedic Prostetic Implantology, RIPO, has been recording all orthopaedic implants of Delta Revison acetabular cup in Emilia Romagna region in Italy. The register has a capture rate of approximately 95% on implants performed in all orthopaedic departments of the Region, both public and private.
Implants of Delta Revision acetabular cup were performed in the period 01 January 2007 – 31 December 2012: failures were recorded until 31 December 2016; the extraction from the register was made on 18 April 2018.
The primary endpoint was the revision of the acetabular cup and/or the insert and the revision of the stem was not considered failure for the acetabular cup.
The data from report ad hoc from RIPO was: 60 implants followed up, 3 for primary surgery and 57 for revision surgery. Mean follow up for revision 7.1 years, 8 revisions.
Therefore, the objectives of this prospective observational study is to assess the performance and safety of Delta Revision acetabular cups, evaluating clinical and radiographic early outcomes of total hip arthroplasty with Delta Revision acetabular cup.

# 2 Objectives

## 2.1 Primary objectives

The primary objective for this study is to assess the clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years.

### 2.2 Secondary objectives

The secondary objectives of the study are as follows:

- To assess the radiographical and clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years;
- To evaluate the safety profile of the DELTA Revision acetabular cup used in real life settings over a period of 5 years;
- To describe baseline data (demographic data, primary diagnosis, aetiology, affected side, type of surgery and intra-operative data) of patients with Delta Revision acetabular cup.

## 3 Study type and design

### 3.1 Overview

This is an observational open label, prospective, longitudinal cohort study designed to reflect real life clinical practice as closely as possible. Thus, clinicians are free to choose the method to implant and total hip arthroplasty in accordance with the current local Delta Revision acetabular cup Indication for Use and current clinical practice.
It is a post-marketing clinical investigation because the product on study is registered, CE marked and used according to the intended use.
The study will enroll approximately 49 adult subjects in whom the decision to implant DELTA Revision acetabular cup must be taken prior to, and independently from the decision to include the patient into the study. This decision should be made in accordance with routine clinical practice and with the Delta Revision acetabular cup Indication for Use at the study site concerned.
The maximum number of visits for each patient is 10 visits, and includes one pre-operative visit (before the Delta Revision acetabular cup implant), intra-operative visit (at the same day of Delta Revision acetabular cup implant), discharge visit (after the Delta Revision acetabular cup implant according to the clinical practice), Follow up visits at 2 months, 6 months, 1 year and 2 years after the implant and, survival Follow-up visits at 3 years, 4 years and, 5 years after the implant.
Clinical data at follow-up can be compared with data collected at pre-operative visit while radiographic data at follow-up can be compared only with data collected at immediate post-op (after surgery).
All eligible patients visiting participating investigators and agreeing to participate in the study will be recruited and monitored throughout the duration of the study.
For each visit and for each single patient, radiographic and clinical data will be assessed up to Follow-up visit 2 years according to the standard of care of the site. These data will be compared to baseline measurements (clinical data at pre-operative visit, while radiographic data at immediate post-operative visit, as baselines, for assessment at follow-up).
For all visits performed by patients and also for the survival Follow-up visits at 3 years, 4 years and, 5 years after the implant, the adverse events and serious adverse events will be collected and assessed: for survival Follow-up period, the assessments can be performed by phone interview if the patient is not present and/or unable to come to the site.

Prior to performing any study related procedures, the subject will need to sign an informed consent document approved by the institutional review board (IRB)/ independent ethics committee (IEC) of the site. The subject will then undergo to pre-operative evaluations which will include medical history, vital signs, physical examination, laboratory assessment, Harris Hip Score (HHS), Oxford Hip Score (OHS), and X-rays evaluation. The pre-operative period may last according to the clinical practice prior to the inclusion of the subject. The subject will be given a 4-digit subject number: the first 2 digits will correspond to the study site number and the last 2 digits will be unique to the subject. The investigator will maintain a screening log to record details of all patients screened and to confirm eligibility or record reasons for screening failure, as applicable.

If the Investigator, despite the patient selection according to study criteria and the preoperative planning, notices any clinical condition or complication not compatible with the study devices before and/or during the surgery, the patient will be considered not included in the study.

Once it has been confirmed that all inclusion criteria are being met and none of the exclusion criteria are being met, the subject will be included into the study. This visit will be considered as Intra-operative visit in which the delta revision acetabular cup will be implanted. The hospitalization period, i.e. the time from the admission to discharge, will last according to the clinical practice.

The subject will return to the site at two months (Follow-Up 2 months), six months (Follow-Up 6 months), twelve months (Follow-Up 12 months) and twenty-four months (Follow-Up 24 months) after the surgery. At each of these visits, the subject will undergo a clinical and radiographical evaluation.

Patients will be followed for safety and survival according to the schedule of assessments for approximately 5 years from the date of the surgery with Delta Revision acetabular cup: in particular at 3, 4 and 5 years after the implant, the patients will undergo the Survival Follow-Up period in which the safety and survivorship of the implant will be evaluated by the site staff. Data collected at each Survival Follow-up visit can be assessed and evaluated by the site staff within a telephone interview and/or a visit at the site according to the clinical practice.

At 3 years, 4 years and 5 years, a phone interview is performed by the Investigator in order to keep in contact with the patient and carry out a brief evaluation of the current status of the hip. The assessment includes some questions about general health status, medical history, feeling and satisfaction about prosthesis. Also the questionnaire OHS has to be performed by phone.

Schedules of assessments are provided in Appendix 1.

### 3.2 Study duration

The expected duration of patient participation in the study will be a maximum of 6 years, with an expected recruitment period of 30 months.

The study will be considered to have started when the first implant will be performed and ended when the last patient has completed the final study assessment visit or phone interview.

# 4 Study endpoints

## 4.1 Primary endpoints

The primary endpoint of the study is the evaluation of Harris Hip Score (HHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant.

## 4.2 Secondary endpoints

The secondary endpoints of the study are as follows:

- Evaluation of Range of Motion (ROM) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant;
- Evaluation of Oxford Hip Score (OHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant;
- Survivorship of the implant (Kaplan-Meier estimate) at 2 years of follow-up after surgery;
- Radiographic implant evaluation and stability assessment of the DELTA Revision acetabular cup as rate of symptomatic radiolucent lines and loosening, at the following timepoints: at discharge, 2 months, 6 months, 1 year, and 2 years after the implant;
- Incidence, type and severity of all Adverse Events (AEs) at intraoperatively/discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant;
- Incidence, type and severity of all Serious Adverse Events (SAEs) at intraoperatively/discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant;
- Incidence, type and severity of all Adverse Device Effects (ADEs) at intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant;
- Incidence, type and severity of all Seriuos Adverse Device Effects (SADEs) at intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant.

# 5 Study population

The patient population for this study will include adult subjects in whom the decision to perform a hip arthroplasty with DELTA Revision acetabular cup must be taken prior to, and independently from the decision to include the patient into the study.

## 5.1 Inclusion criteria

Patients must meet the following criteria for study entry:

1. Male or female.
2. Age ≥ 18 years old.
3. All patients must give written informed consent approved by the study site's Institutional Review Board (IRB)/Ethical Committee (EC).
4. Adult patients in whom a decision has already been made to perform a total hip arthroplasty with DELTA Revision acetabular cup as per indication for use. The decision to implant DELTA

Revision acetabular cup must be taken prior to, and independently from the decision to enroll the patient. This decision should be made in accordance with routine clinical practice at the study site concerned.

5. Patient is able to comply with the protocol.

### 5.2 Exclusion criteria

Patients who meet any of the following criteria will be excluded from study entry.

1. Adult patients with any DELTA Revision acetabular cup contraindication for use as reported in the current local Instruction for use.
2. For female patients, current pregnancy and/or lactation or planning a pregnancy.

### 5.4 Patient Information

Prior to enrolment of a patient in this study, the investigator or designated colleague/clinician will explain the nature and purpose of the data collection to each patient (or patient's legally acceptable representative), in accordance with local policy/guidelines. As all assessments and procedures will be conducted in accordance with routine medical practice at the site, study participation does not convey any additional risks or burdens for the patient. However, the patient will be provided with information on the benefits and risks of their medical treatment. The patient will be required to provide written informed consent to confirm that they allow their medical data to be collected and analysed. This must be obtained prior to study inclusion and any data being entered in the study database. Sufficient time should be allowed to discuss any questions raised by the patient who should be allowed as much time as they need to consider their decision.
The sponsor will provide a sample informed consent form, in language readily understood by the patient. Each patient's original consent form, personally signed and dated by the patient or by the patient's legally acceptable representative, and by the person who conducted the informed consent discussion, will be retained by the investigator. The investigator will supply all enrolled patients with a copy of their signed informed consent. Informed consent forms will not be collected by the sponsor.
If during the study important new information becomes available, the consent form will be revised.

### 5.5 Patient Withdrawal Criteria

The investigator has the right to withdraw a patient from the study at any time. In addition, patients have the right to voluntarily withdraw from the study at any time for any reason. Reasons for withdrawal from the study may include, but are not limited to, the following:

- Patient's pregnancy
- Revision of the implant that requires the DELTA revision acetabular cup removal
- Patient withdrawal of consent at any time
- Any medical condition that the investigator or Sponsor determines may jeopardize the patient's safety if he or she continues in the study

- Investigator or Sponsor determines it is in the best interest of the patient
- The study is closed by the Sponsor and/or by the Ethical Committes/Regulatory Authority
- Repeated patient noncompliance with protocol requirements
- Major protocol violation that may jeopardize the patient's safety according to the Sponsor and Investigator

Every effort should be made to obtain information on patients who withdraw from the study. The primary reason for withdrawal from the study should be documented on the appropriate eCRF and on the patient's medical charts. Patients who withdraw from the study will not be replaced.

Patients who withdraw from the study prematurely will be followed for all unresolved AEs/ADEs and SAEs/SADEs until their resolution or stabilization, the patient is lost to follow-up or dies, or until it is determined that the study participation is not the cause of the AE/SAE/ADE/SADE, whichever occurs first.
If a patient withdraws, data will be collected up to the time of withdrawal, with no additional information collected thereafter. Patients may also request that any previously collected data be excluded from the study.

Note: any withdrawn patients requesting that previously collected data are excluded from the study will be included as enrolled, implanted and withdrawn patients, but no implant or assessment data will be included in the eCRF and these data will be 'missing' in the respective population analyses.

### 5.6 Patient Lost to Follow Up

In the case of patients who do not show up for scheduled visits, site staff should make reasonable efforts (i.e., at least one attempt within a reasonable period of time after a missed visit) to contact these patients for follow-up information. The collection of follow-up data is extremely important for the reliable estimation of study endpoints. Only after sufficient and documented unsuccessful attempts at contact have been made may a patient be declared "lost to follow-up." Such efforts should be documented in the source documents.

### 5.7 Study and site discontinuation

The Sponsor has the right to terminate this study at any time. Reasons for terminating the study may include, but are not limited to, the following:

- The incidence or severity of AEs/ADEs in this or other studies indicates a potential health hazard to patients;
- Patient enrolment is unsatisfactory;
- Inaccurate or incomplete data recording.

The Sponsor will notify the investigator if the study is placed on hold, or if the Sponsor decides to discontinue the study or development program.
The Sponsor has the right to replace a site at any time. Reasons for replacing a site may include, but are not limited to, the following:

- Excessively slow recruitment
- Poor protocol adherence
- Inaccurate or incomplete data recording

# 6 Study device and surgical procedures

## 6.1 Delta Revision acetabular cup

According to the classification criteria reported in annex IX of MDD 93/42 EEC, Delta System is long term implantable device. According to European Directive 2005/50 CE hip devices are re-classified into class III. The Delta System is intended for use in the hip articulation and is a CE marked product.
Delta System is intended to replace the natural acetabulum in total hip arthroplasty (THA). The components are intended for use in cementless applications.
The main goal of a joint prosthesis is to reproduce the articular anatomy, in part or totally. The joint prosthesis is intended to reduce pain and give articular mobility to the patient. The degree of pain reduction and mobility depend, in part, on the preoperative situation, intra-operative options and the post-op rehabilitation.
The Delta System must be used exclusively by orthopaedic surgeons having a good knowledge of the specific surgical techniques: it is indicated for use in total hip arthroplasty.
The Delta System includes acetabular metal shells, e.g. Delta Revision, device object of this study, liners and other accessories such as spacers, hemispheric modules and bone screws.
Study treatment is the hip replacement with implant of DELTA Revision acetabular cup.
The hip replacement may require the implant of additional medical devices and accessories such as:

- liners;
- stems;
- femoral heads;
- spacers;
- hemispheric modules;
- bone screws with diameters of 6,5mm.

All relevant data related to the additional medical devices and accessories the that may be implanted as per Indication for Use, will be collected in order to evaluate the performance and the safety of joint replacement. Data collected can include but not limited to length, batch number, size, material and any other relevant clinical and radiographical assessment.
The Delta Revision acetabular cups with spacers and hemispheric modules are indicated in:

- revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure;
- clinical management problem where arthrodesis or alternative reconstruction techniques are less likely to achieve satisfactory results;
- where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Delta Revision acetabular cup is indicated for revision surgery and bone deficiency treatment both cavitary and segmentary. Primary fixation of the cup is obtained by press-fit, and by bone screws; secondary fixation and osseointegration of the system is guaranteed by a porous Titanium coating.
The caudal hook is intended to be useful also for intra-surgery guide for the restoring of the rotation centre, and it features an adequate conformation in order to avoid an excessive local constraint. The three cranial fins have 7 holes for a further cup stabilization by means of bone screw fixation (**Figure 1**). Six holes are present on the supero-lateral surface as well, to assure a further bone fixation with the use of bone screws. If the hemispheric module is coupled with REVISION system, two of this six holes will be dedicated to the fixation of the module to the cup, by the means of specific-shaped screws.

**Figure 1.** Delta Revision acetabular cup

The material of delta Revision acetabular cup is Titanium coated with PoroTi: more details are available on the corresponding Instructions for Use (IFU).

### 6.1.1 Handling and storage

Delta Revision acetabular cups are provided sterile and should be stored at ambient temperature (indicative range 0-50° C / 32-122°F) in their protective closed packaging in controlled rooms, protected from exposure to light, heat and sudden changes in temperature. Once the package is opened, ensure that both the model and size of the implant correspond to the description printed on the labels. Avoid any contact between the implant and objects or substances that can alter the sterile condition or the surface integrity. Careful visual examination of each implant is recommended before use in order to verify that the implant is not damaged.
Components removed from the package must not be used if they are dropped or suffer other accidental trauma. Devices must not be modified in any way.
The device's code and lot number should need to be recorded in the patient's case history by using the labels included in the component packaging.
The disposal of medical devices is to be performed by the hospitals in conformity with applicable laws.
Re-use of previously implanted devices must be absolutely avoided. Risks associated with reuse of single use devices are:

- infection;
- early or late failure of the device or device fixation;
- lack of appropriate coupling between modular junctions (e.g.: taper connections);
- device wear and wear debris associated complications;
- transmission of diseases (e.g.: HIV, hepatitis);

- immune system response/rejection.

The Delta revision acetabular cup is for single use only. The Instruments used for implantation of the Delta System are reusable surgical instruments.
**Labelling and instructions for use (IFU):** Delta Revision acetabular cup is accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.

### 6.1.2 Sterility

All implantable components of the DELTA Acetabular system are provided sterile with a Sterility Assurance Level (SAL) of $10^{-6}$. Metal components are sterilized by E-beam radiation or EtO and UHMWPE components by EtO. HA coated and Trabecular Titanium implants are sterilized by E-Beam and Gamma radiation. Do not use any component from a package that has been previously opened or appears to be damaged.
**Do not use implants after the expiration date printed on the label.**

## 6.2 Contraindications and risk factors

LimaCorporate delta revision acetabular cups should be implanted only by surgeons familiar with the joint replacement procedures.
Absolute contraindications include:

- local or systemic infection;
- septicaemia;
- persistent acute or chronic osteomyelitis;
- confirmed nerve or muscle lesion compromising hip joint function.

Relative contraindications include:

- vascular or nerve diseases affecting the concerned limb;
- poor bone stock (for example due to osteoporosis) compromising the stability of the implant;
- metabolic disorders which may impair fixation and stability of the implant;
- any concomitant disease and dependence that might affect the implanted prosthesis;
- metal hypersensitivity to implant materials.

The following risk factors may result in poor results with this prosthesis:

- overweight;
- strenuous physical activities (active sports, heavy physical work);
- incorrect implant positioning;
- medical disabilities which can lead to an unnatural gait and loading of the hip joint;
- muscle deficiencies;
- multiple joint disabilities;
- refusal to modify postoperative physical activities;
- patient's history of infections or falls;
- systemic diseases and metabolic disorders;

- local or disseminated neoplastic diseases;
- drug use or alcoholism;
- marked osteoporosis or osteomalacia;
- patient's resistance generally weakened (HIV, tumour, infections);
- severe deformity leading to impaired anchorage or improper positioning of implants.

Adverse effects that most commonly and frequently occur in hip arthroplasty include:

- loosening of the prosthetic components;
- prosthesis dislocation and instability;
- damage to the prosthetic implant;
- instability of the system because of inadequate soft tissue balancing;
- dissociation due to incorrect coupling of the devices;
- infection;
- local hypersensitivity;
- local pain;
- temporary or permanent nerve damage;
- fractures of the devices;
- limb length discrepancies;
- excessive wear of UHMWPE components because of damaged articular surfaces or presence of particles;
- additional surgery;
- blood loss;
- squeaking.

General complications include venous thrombosis with/without pulmonary embolism, cardiovascular disturbances, haematomas, systemic allergic reactions and systemic pain.

## 6.3 Surgical procedures

Pre-operative planning, through radiographic templates in different formats, provides essential information regarding the type and size of components to be used and the correct combination of devices required based on the anatomy and specific conditions of each patient. Inadequate pre-operative planning can lead to improper selection of the implants and/or incorrect implant positioning.
The surgeon should carefully plan the surgery, it is essential for the safety of the device that the covering angle of the cup does not exceed 45° (an angle of 40° is better) and that the angle of ante-version is between 10° and 20°.
Complications or failures of the total hip replacement are more likely to occur in heavy and highly active patients and high offset combinations. The surgeon should perform a careful evaluation of the patient's clinical condition and level of physical activity before performing hip replacement.
The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, that it has a finite expected implant life, and may need to be replaced at some time in the future.
The possible impact of the factors mentioned in sections 7.2 and 7.3.2 should be considered preoperatively and the patient informed as to what steps he/she can take to reduce the possible effects of these factors.

Implants are single use devices; do not re-use implants that were previously implanted in another patient. Do not re-use an implant that has previously come into contact with the body fluid or tissue of another person.
Surgical instruments are subject to wear with normal usage. After extensive use or excessive loads, instruments are susceptible to fracture. Surgical instruments should be used only for their specific purpose. Before use, the functionality of surgical instruments should be checked since the use of damaged instruments may lead to early failure of the implants. Damaged instruments should be replaced before surgery.

### 6.3.1 Intraoperative

The use of trial devices is recommended to check the correct site preparation, size and positioning of the implants to be used. It is recommended that additional implants be available during surgery for use in those cases requiring prostheses of different sizes or when the preoperatively selected prostheses cannot be used.
The correct selection as well as the correct seating/placement of the implant is extremely important. Improper selection, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may negatively affect system performance and survival rate of the implant.
The components forming original LimaCorporate systems must be assembled according to the surgical technique and used only for the labelled indications.
Use only instruments and prosthesis trials specifically designed for use with the implants being used. The use of instruments from other manufacturers or the use of instruments designed for use with other systems can lead to inappropriate preparation of the implant site, incorrect positioning, alignment and fixation of the devices followed by loosening of the system, loss of functionality, reduction of the durability of the implant, and the need for further surgery.
Care must be taken to protect the surfaces involved in the coupling between components (tapers); articular surfaces of the implants must be protected from scratches or any other damage. All component coupling surfaces must be clean and dry before assembly. The stability of component couplings must be verified as described in the surgical technique.

### 6.3.2 Postoperative

Adequate post-operative care should be provided by the surgeon or other suitably qualified medical staff. Regular postoperative x-ray follow-up is recommended to detect any changes in position of the implant or surrounding tissues.
The surgeon should make the patient aware of the limitations of limb function after hip arthroplasty and that the reconstructed joint must be protected from full load bearing for a period of time. Excessive physical activity or trauma to the replaced hip joint can lead to premature failure of the hip arthroplasty through loosening, fracture, or abnormal wear of the prosthetic implants.
The patient should be cautioned by the surgeon to govern activities accordingly and advised that the implants may fail due to excessive joint wear. In particular the following precautions should be presented to the patient by the surgeon:

- avoid repeated high weight-lifting;

- avoid excessive or repeated stair climbing;
- keep body weight under control, overweight conditions may adversely affect the outcomes of joint replacement;
- avoid sudden peak loads (consequences of activities such as running and skiing) or movements which can lead to sudden stops or twisting;
- avoid positions that can increase the risk of dislocation.

Lack of appropriate post-operative rehabilitation instructions and care can negatively influence the outcome of the surgical procedure.

# 7 Study assessment

All patients will be closely monitored for safety and the evaluation of the implant status during all study: The timing of study visits will be in accordance with current local practice at the study site, but the following timelines and temporal window will be followed:

- Pre-operative visit: timing is in accordance with current local practice
- Intraoperative visit: in accordance with current local practice
- Discharge visit: the time from admission date to the discharge will be based according to the current clinical practice and both dates will be entered in the eCRF
- Follow-Up 2 months: ± 30 days
- Follow-Up 6 months: ± 60 days
- Follow-Up 12 months: ± 6 months
- Follow-Up 24 months: ± 6 months
- Survival Follow-Up visit at 3,4 and 5 years: ± 6 months

Study assessments are outlined in this section and in Appendix 1.

## 7.1 Informed consent process

An IRB/IEC approved informed consent form will be read, signed and dated by the subject prior to the performance of any study related procedures. Prior to obtaining informed consent, the investigator (or designate) will explain the nature and the purpose of the study to the subject, provide the subject ample time to consider his/her decision and answer any questions posed by the subject to his/her satisfaction. Please see section 12.2 for more details.

## 7.2 Medical History and Demographic Data

Medical history includes clinically significant diseases, hip history (including all prior hip therapies and procedures), osteoporosis history (including assessment, treatment and nature of the osteoporosis) , and all medications (e.g., prescription drugs, over-the-counter drugs, herbal/homeopathic remedies, pain medication) used by the patient prior to the pre-operative visit. The affected limb (right or left) is also requested to be collected in the eCRF and to be reported clearly in the medical charts.

Demographic data will include age, sex, ethnicity, smoking and drinking habits, activity level (e.g. sedentary, normal, intense) and, working status (active worker or retired).
Medical history and demographic data will be collected only at the pre-operative visit.

### 7.3 Vital Signs

Body height and body weight will be recorded only at the pre-operative visit and collected in the eCRF. Vital signs (body temperature, pulse, blood pressure) and ECG will be performed in accordance with current local practice at the study site and will not collected in the eCRF but it is very recommended to store and archive all reports in the medical charts. Significant and severe abnormal vital signs at any time during the course of study should be recorded as AEs or SAEs.
The Sponsor will calculate the BMI (body max index) automatically and will be reported in the eCRF.

### 7.4 Physical examination

A complete physical examination will be carried out at the pre-operative visit. This will include an assessment of all major systems as well as an assessment of the general appearance, lung/chest, abdomen, extremities and musculoskeletal.

Brief physical examination will be carried out at Follow-Up 2 months, 6 months, 12 months and 24 months. It will include a brief assessments of hip, extremities and musculoskeletal. Significant and severe abnormal physical examination at any time during the course of study should be recorded as AEs or SAEs.

### 7.5 Routine laboratory evaluations

Routine laboratory evaluations (e.g., haematology and serum chemistry) will be performed in accordance with current local practice at the study site and will not collected in the eCRF but it is very recommended to store and archive all laboratory reports in the medical charts. Significant and severe abnormal laboratory evaluations at any time during the course of study should be recorded as AEs or SAEs.

### 7.6 Clinical and Functional evaluation

Clinical evaluation will be performed at the following visits:

- Pre-operative visit: preoperative assessment will be used as baseline values for score improvement
- Intraoperative visit/ Discharge visit
- Follow-Up 2 months: ± 30 days
- Follow-Up 6 months (± 60 days)
- Follow-Up 12 months (± 6 months)
- Follow-Up 24 months (± 6 months)

- Survival Follow-Up visit at 3,4 and 5 years (± 6 months): Clinical evaluation with HHS and ROM shall be assessed only if the patients come to the hospital; clinical evaluation is not applicable if the patient does not come for a visit as side; only telephone interview with the OHS shall be performed at 3, 4, and 5 years.

Data collected at the visits outlined in Appendix 1 will be recorded in the eCRF. Many of the assessments used in standard practice are included in the clinical evaluation. Full details of the instruments used in this study are provided in Appendices 3 and 4.
Harris Hip Score and Oxford Hip Score will be used and evaluated for this study as detailed in the sections 7.6.1 and 7.6.2.

### 7.6.1 Harris Hip Score (HHS) and Range of motion (ROM) [6]

The Harris Hip Scale (HHS) was developed for the assessment of the results of hip surgery, and it is intended to evaluate various hip disabilities and methods of treatment in an adult population. The original version was published 1969. The HHS is an outcome measure administered by a qualified health care professional, such as a physician or a physical therapist.
No training is required to administer the HHS and it requires very little time or equipment to complete. There are ten items covering four domains. The domains are pain, function, absence of deformity, and range of motion. [7]
The pain domain measures pain severity and its effect on activities and need for pain medication. The function domain is divided into daily activities and gait. The deformity domains observes hip flexion, adduction, internal rotation, and extremity length discrepancy while the range of motion domain asses hip ROM. [8]
The HHS is divided into three sections. The first section are questions about pain and its impact which are answered by the patient. The second and third sections require the physiotherapist/Investigator to assess the patient or client's hip joint and function. [9]
The HHS is a measure of dysfunction so the higher the score, the better the outcome for the individual. Results can be calculated and must to enter in the eCRF.
The maximum score of the absolute HHS is 100 points. Pain domain contributes 44 points, function 47, ROM 5 and absence of deformity 4 points. Function is subdivided into gait and activities of daily living. Calculation of the ROM score includes splitting the motion into categories based on utility and then multiplying the degrees of motion with a given index factor. The index scores are then added and multiplied by a factor of 0.05 to obtain the final ROM score.
Results can be interpreted with the following:

- < 60 = failed result;
- 60-69 = poor result;
- 70–79 = fair;
- 80–90 = good;
- 90–100 = excellent;

The outcome is considered satisfactory for values over 80.
The weighted HSS score is calculated as a percentage of normal values relative to gender and age.
Harris Hip Score will be performed at pre-operative visit, discharge visit and, follow-Up 2 months (± 30 days), follow-Up 6 months (± 60 days), follow-Up 12 months (± 6 months) and follow-Up 24 months (± 6 months) since the date of the surgery.

Harris Hip Score is detailed in the Appendix 3.

### 7.6.2 Oxford Hip Score (OHS)

The Oxford Hip Score (OHS) is a joint-specific, patient-reported outcome (PRO) measure, or PROM, designed to assess disability in patients undergoing total hip replacement (THR) [10]. It was developed in 1996 to be simple to administer in order to facilitate use, with new scoring introduced in 2007.
The OHS is a short 12-item survey that can be done with pen and paper. Patients are asked to reflect on their pain and functional ability over the previous weeks. There are two domains (pain and function) with six items or questions in each, using the following scoring: each question has been scored between 0 and 4, with 4 being the best outcome, producing overall scores running from 0 to 48, with 48 being the best outcome. The calculation of the total score of OHS is based on this scoring system, with a score reported as excellent for more than 41 points, good from 34 to 41, fair from 27 to 33 and poor for less than 27. [11]
Oxford Hip Score will be performed at pre-operative visit, discharge visit and, follow-Up 2 months (± 30 days), follow-Up 6 months (± 60 days), follow-Up 12 months (± 6 months) and follow-Up 24 months (± 6 months) since the date of the surgery. During the Survival Follow-up period [3 years (± 6 months), 4 years (± 6 months) and, 5 years (± 6 months)] since the date of the delta revision acetabular cup implant, it is recommended to perform the questionnaires by phone if applicable and to report them in the medical charts and in the eCRF.
Oxford Hip Score is detailed in the Appendix 4.

## 7.7 Radiographical evaluation

Imaging will be collected to evaluate the radiographic performance of the device, which will contribute to the overall efficacy evaluation of Delta Revision acetabular cup.
The safety guidelines and intervention for X-rays at the site should be followed according to the Hospital procedure and clinical practice to ensure the safety for subjects, radiologists, site staff personnel and technicians. It is the site responsibility to check that the subject is able to have X-rays and that there is no contraindication to perform the X-ray.
Only anonymized X-rays performed will be accepted. Use the same modality for acquiring X-rays and collect all data requested below for each subject included in the study.
In compliance with privacy laws to ensure and protect the confidentiality of the subject, no subject names or identifiers should be entered into the electronic header. The information requested below has to be entered into the electronic header in lieu of subject identifiers:

- Study name (H-34, Delta Revision)
- Subject ID (Site number-XX where XX is a progressive number according to each subject included at the site)
- Date of X-ray execution

The anonymized X-rays data have to be uploaded directly in the eCRF.
Limacorporate will ensure that all images will be handled appropriately to ensure confidentiality of any subject and site information. It is expected that all data sent to Limacorporate will be collected in compliance with local regulatory laws and that all confidential subject identifiers will be removed by the

site before they are sent to Limacorporate. Access to images and associated study data will be restricted to authorized personnel only. All data and materials will be considered the exclusive, confidential property of LimaCorporate. All image analysis and data management will be performed by LimaCorporate in accordance with established and audited Standard Operating Procedures (SOPs). All electronic data and audit trails will be redundantly archived to prevent loss of data.

All X-rays performed during the clinical study fall within standard clinical practice.

Radiological assessment was carried out preoperatively and postoperatively at discharge, at 2 months, 6 months, 12 months, and 24 months after surgery. It included standard views, such as antero-posterior (AP) of the pelvis, antero-posterior (AP) and lateral (LAT) of the affected hip.

Any presence of cysts, osteophytes, sclerosis calcifications, or any other joint features that may be relevant for preoperative evaluation were reported.

Acetabulum was divided into three Regions of Interest (ROI) according to DeLee and Charnley [12].

Radiolucent lines were evaluated according to their presence, absence, location and thickness (e.g. <1 mm, 1 to 2 mm or >2 mm). An acetabular component was considered at risk of loosening when either a radiolucent line ≥2 mm was present in 2 or more of the 3 zones, or if there was an evidence of migration of the component.

Postoperative radiographs at discharge were used as baseline to evaluate radiolucent lines progression and to assess the initial angle of abduction and the initial postoperative fit of the cup.

Evidence of osteolysis (location), sclerosis, atrophy (location), ectopic bone formation (Brooker classification, [13]), dislocation and subluxation were recorded.

Concerning the femoral side, postoperative and follow-up X-rays were reviewed for implant positioning and stem alignment. Stem sizing was considered as normal, undersized or oversized, in relation to the endosteal cortex at the resection level. Stem position was evaluated as neutral, varus or valgus. Presence, location and thickness of radiolucent lines, osteolysis, atrophy, sclerosis, calcar resorption and cortical hypertrophy were reported according to Gruen zones [14]. Radiolucent lines were measured as being either 1 or 2 mm or > 2 mm in size, and considered to be significant, if they affected more than 50% of any zone. Sclerosis was evaluated if present as slight, moderate, marked.

Cortical hypertrophy was recorded as either present or absent and considered significant if it affected more than one third of the stem length. Osteolysis was analyzed as any area of non-linear radiolucency more than 2 mm surrounding the prosthesis.

Subsidence, medial or lateral tilt, stress shielding, heterotopic ossifications, bone fractures were analyzed. Subsidence was measured as a change in the distance between the upper part of the greater trochanter and the lateral shoulder of the femoral stem. It was considered significant if a difference greater than 3 mm existed between subsequent follow-ups. Loosening, migration, stem breakage, if present, were reported.

The imaging schedule for this study is presented in **Errore. L'origine riferimento non è stata trovata.** and appendix 2. Only X-rays were collected for each subject included into the trial.

X-Ray (Antero-Posterior view) has to be performed at preoperative visit, at immediate postoperative and at every follow up visit and uploaded in the eCRF.

It is very recommended to perform the X-ray (lateral view) and if it is performed to upload in the eCRF and, to archive all related reports in the medical charts.

| X-RAY: VIEW | PREOP | AT DISCHARGE | MONTH 2 | MONTH 6 | MONTH 12 | MONTH 24 |
|---|---|---|---|---|---|---|
| AP Pelvis | ✕ | ✕ | ✕ | ✕ | ✕ | ✕ |
| Lateral Hip | – | – | – | – | – | – |

**Table 1**: Schedule of Imaging Studies and Examination Intervals

✕ Required;

– Not Required.

Radiographic evaluation includes the assessment of radiolucency lines, loosening and Heterotopic Ossification.

The following measurements will be collected in the eCRF and reported in the medical charts at each visit after the implant as reported in Table 1 and appendix 2:

- Heterotopic Ossification
- Acetabular Inclination
- Acetabular Anteversion
- Acetabular Component Radiolucency
- Acetabular Component Migration
- Dislocation
- Infection

### 7.7.1 Heterotopic Ossification

Heterotopic Ossification consists of the development of bone outside its normal location in the skeleton. Heterotopic Ossification will be graded from AP view following the Brooker classification [13]:

0. **Grade 0:** No evidence of Heterotopic Ossification;
1. **Grade 1:** one or two foci of Heterotopic Ossification less than 1 cm each;
2. **Grade 2:** ossification or osteophytes occupying less than half the space between the femur and pelvis;
3. **Grade 3:** ossification or osteophytes occupying more than half the space between the femur and pelvis;
4. **Grade 4:** ossification that bridges the pelvis and femur.

### 7.7.2 Acetabular Inclination

Acetabular Inclination is defined from the AP Pelvis view and consists of the angle between the articular side of the acetabular cup and the transverse axis [15]. Acetabular Inclination will be measured using the following procedure:

**Line 1:** a line is drawn through the medial and lateral margins of the femoral cup (Line 1 in **Figure 2**).

**Line 2:** Line 2 in Figure 2 consists of the transverse pelvic axis along the transischial tuberosity line.

Acetabular Inclination will be obtained measuring the angle between Line 1 and Line 2.

The normal range of inclination is between 30 and 50°. Smaller angles provide a stable hip but a reduced abduction. Greater angles are associated with greater risk of hip dislocation.

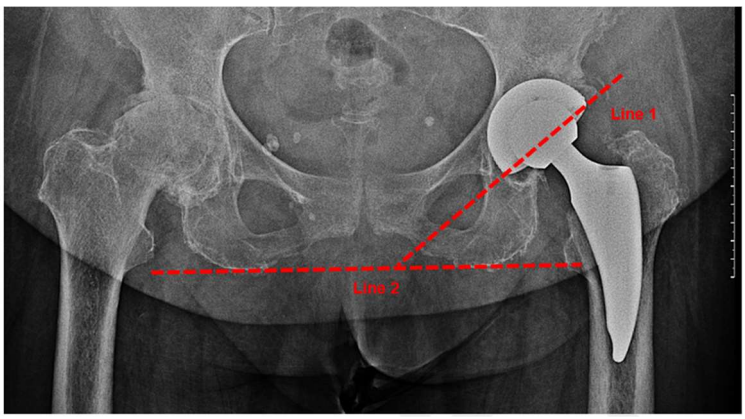


**Figure 2**: acetabular inclination

### 7.7.3 Acetabular Anteversion

Acetabular Anteversion is defined on a lateral view by the angle between the acetabular axis and the coronal plane [15] [16]. Acetabular Anteversion will be measured using the following procedure:

**Line 1:** the acetabular line is drawn tangential to face of acetabulum, along the medial and lateral margins of the cup (black Line 1 in **Figure 3**).

**Line 2:** Line 2 in **Figure 3** corresponds to a line perpendicular to the horizontal plane, which intersects Line 1.

Acetabular Anteversion is obtained by measuring the angle between Line 1 and Line 2.

Normal value ranges from 5° to 25° anteversion as this allows adequate flexion of the hip.

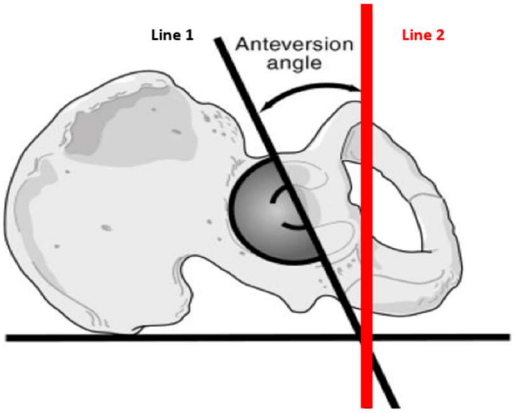


**Figure 3**: acetabular anteversion

### 7.7.4 Acetabular Component Radiolucency

Radiological assessment includes standard views as antero-posterior (AP) radiograph of the pelvis and antero-posterior (AP) and lateral (LAT) of the affected hip at the preoperative time, at the postoperative one and after 2 months, 6 months, 12 months, 24 months from surgery.

Acetabular component is divided into 3 regions of interest according to DeLee-Charnley [12]. Radiolucent lines are evaluated according to their presence, absence, location and thickness; Acetabular Component Radiolucency will be graded in accordance with the following definitions from the AP view:

**0. None:** No evidence of radiolucency.

**1. < 1 mm:** Presence of radiolucency <1 mm in thickness.
**2. ≥1 to <2 mm:** Presence of radiolucency ≥1 to <2 mm in thickness.
**3. ≥2:** Presence of radiolucency ≥2 in thickness.
An acetabular component is considered at risk for clinical loosening when a lucent line > 2 mm or greater is present in 2 or more of 3 zones or if there's an evidence of migration of the component.
Progression of radiolucent lines is evaluated by comparing postoperative x-ray with the previous recent ones.
Postoperative radiographs at discharge are used as baseline for evaluation and are used to assess the initial angle of abduction of the cup and the initial postoperative fit of the cup as manifested as radiographic evidence of interface "gaps".
If a zone contains multiple radiolucencies, the width of the lucency that predominates in that zone will be categorized. Acetabular component radiographic zones are shown in **Figure 4**.

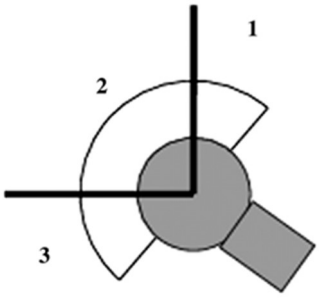


**Figure 4:** acetabular radiolucency zone

### 7.7.5 Acetabular Component Migration

Acetabular Component Migration will be graded from AP view in accordance with the following definitions [17]:
0. **Absent:** No evidence of a change in position of the acetabular component relative to the native bone stock ≥2 mm.
1. **Present:** Presence of a change in position of the acetabular component relative to the native bone stock ≥2 mm.
**Migration:** Decimal value (mm).
Acetabular Component Migration will be assessed relative to discharge or the next available post-operative time-point.
The threshold for significance is 2 mm. According to a general consensus [12] [17] [18] [19], a complete, concentric radiolucency of 2 mm indicates a "loose" prosthesis.

### 7.7.6 Dislocation

Dislocation occurs if the head moves out of the acetabular component for any reason and will be graded from AP view in accordance with the following definitions:
**0. Absent:** No evidence of dislocation.
**1. Present:** Presence of dislocation.

### 7.7.7 Infection

Radiographic findings suggestive of Infection can vary from completely normal to frank bone destruction mimicking loosening or particle disease, also including a wide irregular radiolucency at the metal-bone interface. Infection will be graded from AP view in accordance with the following definitions:

**0. Absent:** No evidence of infection.

**1. Present:** Presence of infection.

Usually previous radiographs are necessary for comparison, if available.

**Infections have to be reported also in the eCRF as AE and or SAE (if the infection reflect the SAE requirements, see section 9) including patient's symptoms, medications and/or surgery procedures performed if applicable.**

## 7.8 Surgical procedures and implant data

Surgical procedures will be performed according to a proper standardized surgical technique by orthopaedic surgeons qualified by training, experienced in joint replacement procedures, and familiar with the appropriate use of the components involved in this clinical evaluation. Anaesthesia, post-operative pain management, and prophylactic antibiotics will be done according to the site clinical practice: although these data will be not collected in detail in the eCRF, all documentation has to be archive at the site and be available for the review.

Surgery data includes date of surgery, surgical approach, surgery time and intra-operative and immediate post-operative haematocrit measurements.

Implant data for Delta Revision acetabular cup include the type, size, material, batch number and expire date: the label of acetabular cup implanted has to be archived also in the source documents.

All above mentioned data for surgery and device have to be collected in the eCRF.

At the immediate post-operative visit an AP X-ray view of the hip has to be obtained in order to have useful information for implant size and for determining the correct implant placement for the patient's hip pathology: this X-ray will related data will be uploaded in the eCRF.

# 8 Timing of study assessments

## 8.1 Pre-operative assessment

Written informed consent for participation in the study must be obtained before performing any study-specific evaluations. Informed Consent Forms for included patients and for patients who are not subsequently included will be maintained at the study site.

All pre-operative evaluations must be completed and reviewed to confirm that patients meet all eligibility criteria before the inclusion.

The pre-operative period may last according to the clinical practice prior to the inclusion of the subject.

The subject will be given a 4-digit subject number: the first 2 digits will correspond to the study site number and the last 2 digits will be unique to the subject.

If the Investigator, despite the patient selection according to study criteria and the preoperative planning, notices any clinical condition or complication not compatible with the investigational devices before/during the surgery, the patient will be considered screening failure.
The investigator will maintain a screening log to record details of all patients screened and to confirm eligibility or record reasons for screening failure, as applicable.
Please see Appendix 1 for the schedule of screening and pre-operative assessments.

### 8.2 Intra-Operative assessment

Once it has been confirmed that all inclusion criteria are being met and none of the exclusion criteria are being met, the subject will be included into the study. This visit will be considered as Intra-operative visit in which the delta revision acetabular cup will be implanted. The hospitalization period, i.e. the time from the admission to discharge, will last according to the clinical practice.
Regarding to the intra-operative phase, the following data will be collected: date of surgery, surgical approach and technique, anaesthesia details, surgery time and intra-operative and immediate post-operative haematocrit measurements.
Implant data for Delta Revision acetabular cup include the type, size, material, batch number and expire date: it is very recommended to archive in the source documents the label of acetabular cup implanted.

### 8.3 Assessment during the Follow-up period

The follow-up period begins from the date of the surgery independently from the timing of admission and discharge based according to the current clinical practice.
The subject will return to the site at two months (Follow-Up 2 months), six months (Follow-Up 6 months), twelve months (Follow-Up 12 months) and twenty-four months (Follow-Up 24 months) after the surgery. At each of these visits, the subject will undergo a clinical and radiographical evaluation. All assessments will be performed on the day of the specified visit unless a time window is specified in section 10 and appendix 1.
Please see Appendix 1 for the schedule of assessments performed during the study follow-up period.
Please see Appendix 2 for the schedule of assessments for radiographical evaluation.

### 8.4 Assessment during the Survival Follow-up period

The Survival follow-up period begins from the date of the surgery independently from the timing of admission and discharge (based according to the current clinical practice) and the timing of follow-up period.
Patients will be followed for safety and survival according to the schedule of assessments for approximately 5 years from the date of the delta revision acetabular cup implant: in particular at 3, 4 and 5 years after the implant, the patients will undergo in the Survival Follow-Up period in which the safety and survivorship of the implant will be evaluated by the site staff. Data collected at each Survival

Follow-up visit can be assessed and evaluated by the site staff within a telephone interview and/or a visit at the site according to the clinical practice.
If in the case, at 3 years, 4 years and 5 years, a phone interview is performed by the Investigator in order to keep in contact with the patient and carry out a brief evaluation of the current status of the hip. The assessment includes some questions about general health status, medical history, feeling and satisfaction about prosthesis. Also the PROMs, OHS has to be evaluated by phone and reviewed by the Investigator.
Patients will be followed for all unresolved or new AEs/ADEs and SAEs/SADEs until their resolution or stabilization, the patient is lost to follow-up or dies, whichever occurs first.
If the Suvival Follow-up visits will be performed at the Hospital, the Investigator has to perform all assessment required during the Follow-up visits.

### 8.5 Assessment at unscheduled visit

In case unplanned visits are required, Electronic Case Report Form (eCRF) pages will be available to report the information collected during those visits.

## 9 Safety Parameters and definition

Safety assessments will consist of monitoring and recording adverse events (AEs), including serious adverse events (SAEs), device deficiencies (DDs) and, adverse device effects (ADEs) including serious adverse device effect (SADEs); they are deemed critical to the safety evaluation of the study in the same way as the Unanticipated Serious Adverse Device Effects (USADEs).
Certain types of events require immediate reporting to the Sponsor, as outlined in Section 9.4.

### 9.1 Adverse Events

An adverse event (AE) 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. This definition includes events related to the investigational medical devices or events related to the procedures involved. An AE can therefore be any of the following:

- Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical device, whether or not considered related to the medical device;
- Any new disease or exacerbation of an existing disease (a worsening in the character, frequency, or severity of a known condition);
- Recurrence of an intermittent medical condition (e.g., headache) not present at pre-operative visit (baseline);

- Any deterioration in a laboratory value or other clinical test (e.g., ECG, X-ray) that is associated with symptoms or leads to a change in concomitant treatment and/or medical device implant;
- AEs that are related to a protocol-mandated intervention, including those that occur prior to the medical device implant (e.g., pre-operative invasive procedures such as X-rays)

### 9.2 Adverse Device Effects

An adverse device effect (ADE) is an adverse event related to the use of the investigational medical devices**.** This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical devices. This definition includes any event resulting from use error or from intentional misuse of the investigational medical devices.

### 9.3 Device Deficiency

A device deficiency is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance, including the malfunctions, use errors, and inadequate labelling.
**A device deficiency that has resulted and/or will led in any of the consequences characteristic of a serious adverse event is required to be reported by the investigator to the Sponsor within 24 hours after learning of the event**.

### 9.4 Serious Adverse Events (immediately reportable to the Sponsor)

A Seriuos Adverse Event (SAE) is any AE that meets any of the following criteria:

- led to death;
- led to serious deterioration in the health of the subject, that either resulted in a life-threatening illness or injury;
- led to serious deterioration in the health of the subject, that resulted in a permanent impairment of a body structure or a body function;
- led to serious deterioration in the health of the subject, that resulted in hospitalization or prolongation of patient hospitalization;
- led to serious deterioration in the health of the subject, that resulted in a medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
- led to serious deterioration in the health of the subject, that resulted in a chronic disease;
- led to foetal distress, foetal death or a congenital abnormality or birth defect;
- any revision of the implant independently if it requires the DELTA revision acetabular cup removal

The terms “severe” and “serious” are not synonymous. Severity refers to the intensity of an AE (rated as mild, moderate, or severe); the event itself may be of relatively minor medical significance. Severity and seriousness need to be independently assessed for each AE recorded on the eCRF.
Serious AEs are required to be reported by the investigator to the Sponsor within 24 hours after learning of the event (see Section 9.8 for reporting instructions).

## 9.5 Serious Adverse Device Effects (immediately reportable to the Sponsor)

A Serious adverse device effect (SADE) is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event (see Section 9.4).

## 9.6 Unanticipated Serious Adverse Device Effects (immediately reportable to the Sponsor)

Any serious adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that related to the rights, safety or welfare of the subject.

## 9.7 Methods and timing for capturing and assessing safety parameters

The investigator is responsible for ensuring that all AEs (see Section 9.1 for definition) are recorded on the AE eCRF and reported to the Sponsor in accordance with instructions provided in this section and in Section 9.8 through Section 9.10.
For each AE recorded on the AE eCRF, the investigator will make an assessment of seriousness (see Section 9.4 for seriousness criteria), severity (see Section 9.7.2), and causality (see Section 9.7.3).

### 9.7.1 Adverse event reporting period

Investigators will seek information on AEs at each patient contact. All AEs, whether reported by the patient or noted by study personnel, will be recorded in the patient’s medical record and on the AE eCRF.
**After informed consent** has been obtained but prior to medical device implant, only SAEs caused by a protocol-mandated intervention should be reported (e.g., SAEs related to invasive procedures).
**After and during the implant**, all DDs, ADEs and AEs regardless of relationship to medical device, will be reported until the event has subsided or values have returned to baseline, or in the case of permanent impairment, till the condition stabilizes. If an adverse event is assessed as a serious adverse event, it must be reported as an SAE (see Section 9.8 for reporting instructions), per the definition of SAE in Section 9.4.
At each study visit, all AEs that have occurred since the previous visit must be recorded in the adverse event form of the subject’s CRF.

Patients who withdraw from the study prematurely will be followed for all unresolved AEs/ADEs and/or SAEs/SADEs until their resolution or stabilization, the patient is lost to follow-up or dies, or until it is determined that the study participation is not the cause of the AE/SAE/ADE/SADE, whichever occurs first .

### 9.7.2 Assessment of severity of Adverse events

A consistent methodology of non-directive questioning should be adopted for eliciting AE information at all patient evaluation time points. Examples of non-directive questions include the following:
"How have you felt since your last clinic visit?"
"Have you had any new or changed health problems since you were last here?"
The Investigators should be assessed the severity for AEs according to the following table:

| Grade | Severity |
|---|---|
| **Mild** | The adverse event is transient and easily tolerated by the subject; asymptomatic or mild symptoms; clinical or diagnostic observations only; or intervention not indicated. |
| **Moderate** | The adverse event causes the subject discomfort and interferes somewhat with his/her daily activities; minimal, local, or non-invasive intervention indicated; or limiting age-appropriate instrumental activities of daily living. [a] |
| **Severe** | The adverse event causes significant discomfort to the subject and interferes significantly with his/her daily activities; medically significant, but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; or limiting self-care activities of daily living.[b] |

[a] Instrumental activities of daily living refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
[b] Examples of self-care activities of daily living include bathing, dressing and undressing, feeding one's self, using the toilet, and taking medications, as performed by patients who are not bedridden.

If an event is assessed as a "significant medical event," it must be reported as an SAE (see Section 9.8 for reporting instructions), per the definition of SAE in Section 9.4.

### 9.7.3 Assessment of causality of Adverse events

Investigators should use their knowledge of the patient, the circumstances surrounding the event, and an evaluation of any potential alternative causes to determine whether or not an AE is considered to be related to the medical device, indicating "yes" or "no" accordingly. The following guidance should be taken into consideration:

- Temporal relationship of event onset to the implant of the medical device
- Known association of the event with the medical device or with similar surgical procedures
- Known association of the event with the disease under study
- Presence of risk factors in the patient known to increase the occurrence of the event
- Presence of other related factors that are known to be associated with the occurrence of the event

The causal relationship between AE and the medical device will be determined by the investigator based on his or her clinical judgment and classified into one of the following:

- Related
- Not related

Investigators should use correct medical terminology/concepts when recording AEs on the AE eCRF. Avoid colloquialisms and abbreviations.
Only one AE term should be recorded in the event field on the AE eCRF.
In general, AEs occurring secondary to other events (e.g., cascade events or clinical sequelae) should be identified by their primary cause, with the exception of severe or serious secondary events. However, medically significant AEs occurring secondary to an initiating event that are separated in time should be recorded as independent events on the AE eCRF.
All AEs should be recorded separately on the AE eCRF if it is unclear as to whether the events are associated.
A persistent AE is one that extends continuously, without resolution, between patient evaluation time points. Such events should only be recorded once on the AE eCRF.
The initial severity of the event should be recorded, and the severity should be updated to reflect the most extreme severity any time the event worsens. If the event becomes serious, the AE eCRF should be updated to reflect this.
A recurrent AE is one that resolves between patient evaluation time points and subsequently recurs. Each recurrence of an AE should be recorded separately on the AE eCRF.
A preexisting medical condition is one that is present at the pre-operative visit for this study.
Such conditions should be recorded on the Medical History and Baseline Conditions eCRF.
A preexisting medical condition should be recorded as an AE only if the frequency, severity, or character of the condition worsens during the study. When recording such events on the AE eCRF, it is important to convey the concept that the pre-existing condition has changed by including applicable descriptors (e.g., “worsening of headaches”).

### 9.7.4 Death

Deaths that occur during the protocol specified AE reporting period (see Section 9.7.1), regardless of relationship to study device, must be recorded on the AE eCRF and immediately reported to the Sponsor (see Section 9.8).
Death should be considered an outcome and not a distinct event. The event or condition that caused or contributed to the fatal outcome should be recorded as the single medical concept on the AE eCRF as Serious Adverse Event and immediately reported to the Sponsor (see Section 9.8).

### 9.7.5 Patient-reported outcome data

AE reports will not be derived from questionnaires. However, if any patient responses suggestive of a possible AE are identified during site review of the questionnaires, site staff will alert the investigator, who will determine if the criteria for an AE have been met and will document the outcome of this assessment in the patient's medical record per site practice. If the event meets the criteria for an AE, it will be reported on the AE eCRF.

## 9.8 Immediate reporting requirements from Investigator to Sponsor

The investigator must report the following events to the Sponsor within 24 hours after learning of the event, regardless of relationship to study medical device:

- SAEs
- SADEs
- USADEs
- DDs that could led to a SAE

The investigator must report new significant follow-up information for these events to the Sponsor within 24 hours after becoming aware of the information. New significant information includes the following:

- New signs or symptoms or a change in the diagnosis
- Significant new diagnostic test results
- Change in causality based on new information
- Change in the event's outcome, including recovery
- Additional narrative information on the clinical course of the event

Investigators must also comply with local requirements for reporting serious AEs to the local health authority and IRB/EC.

For reports of SAEs, SADEs and, DDs that could led to a SAE, investigators should record all case details that can be gathered within 24 hours on the AE eCRF and submit the report via the electronic data capture (EDC) system. A report will be generated and sent to LimaCorporate by the EDC system.

In the event that the EDC system is unavailable, a paper SAE form should be completed and sent by e-mail (clinical.research@limacorporate.com) within 24 hours after learning of the event. Once the EDC system is available, all information will need to be entered and submitted via the EDC system.

## 9.9 Follow-up of patient after adverse events

### 9.9.1 Investigator Follow-Up

The investigator should follow each AE until the event has resolved to baseline grade or better, the event is assessed as stable by the investigator, the patient is lost to follow up, or the patient withdraws consent. Every effort should be made to follow all serious AEs considered to be related to study device or trial-related procedures until a final outcome can be reported.

During the study period, resolution of AEs (with dates) should be documented on the AE eCRF and in the patient's medical record to facilitate source data verification. If, after follow-up, return to baseline status or stabilization cannot be established, an explanation should be recorded on the AE eCRF.

**All ADE that result in a participant's withdrawal from the study or are present at the end of the study, should be followed up until a satisfactory resolution occurs.**

Patients who withdraw from the study prematurely will be followed for all unresolved AEs/ADEs and/or SAEs/SADEs until their resolution or stabilization, the patient is lost to follow-up or dies, or until it is determined that the study participation is not the cause of the AE/SAE/ADE/SADE, whichever occurs first .

### 9.9.2 Sponsor Follow-Up

For SAEs, SADEs, USADEs and, DDs that could led to a SAE, the Sponsor or a designee may follow up by telephone, fax, electronic mail, and/or a monitoring visit to obtain additional case details and outcome information (e.g., from hospital discharge summaries, consultant reports, autopsy reports) in order to perform an independent medical assessment of the reported case. Additional material, if already obtained to evaluate the event, may be requested for review by the Sponsor.

## 9.10 Survival period adverse events

During survival follow-up, the investigator should instruct each patient to report to the investigator any subsequent AEs that the patient's personal physician believes could be related to study medical device or study procedures.
The investigator should notify the Sponsor of any death, SAE, SADE or other AE of concern occurring at any time during the survival if the event is believed to be related to prior study medical device or study procedures.
The investigator should report these events to Limacorporate on the AE eCRF.

## 9.11 Expedited reporting to Health Authorities, Investigators, Institutional Review Boards, and Ethics Committees

To determine reporting requirements for single AE cases, the Sponsor will assess the expectedness of these events.
The Sponsor will compare the severity of each event and the cumulative event frequency reported for the study with the severity and frequency reported in the applicable reference document.
Reporting requirements will also be based on the investigator's assessment of causality and seriousness, with allowance for upgrading by the Sponsor as needed.
The Sponsor will monitor the incidence of these expected events during the study.

# 10 Statistical considerations

All analyses will be performed using SAS version 9.3 or higher.

## 10.1 Primary endpoint

The primary endpoint is to assess the change in the Harris Hip Score (HHS) from pre-operative baseline up to 2 years after surgery. A 20 point increase in the HHS is considered a minimal clinically relevant change for the purposes of this study. The specific hypotheses to be tested are:

$Ho: \overline{D} \leq 20$

$Ha: \overline{D} > 20$

where

$$\overline{D} = \left( \sum_{i=1}^{n} HHS_{2\,Year,i} - HHS_{Baseline,i} \right) / n$$

### 10.2 Baseline variables

All baseline variables will be summarized using descriptive statistics. Continuous variable will be summarized using the mean, standard deviation, N, and range. Categorical variable will be summarized frequencies and proportions.

### 10.3 Determination of sample size

A review of the literature [8] indicated that a minimal clinically important increase in Harris Hip Score is approximately 20 points. As well, the variation of the score at each time point measured was approximately 15 points. For the purposes of sample size calculation the observed increase in HHS is assumed to be 32 points, the Type I error rate was set to 0.05 and the correlation between the paired observations from baseline to 2 years was assumed to be zero due to the length of time between the two observations. A standard one-sided paired T-test with a sample size of 29 pairs will afford 90% power to detect an increase of 20 points on the HHS test. Assuming a 40% loss to follow-up, total enrolment for this study is set at 49 subjects.

### 10.4 Statistical methods

Statistical analyses will be performed by an external contract research organisation (CRO) and/or consultant, managed by the Sponsor.

Primary Endpoint

For the primary endpoint, a standard one-sided paired T-test will be used to test the hypotheses shown above in section 10.1. The test statistic is:

$$t = \frac{\overline{D} - 20}{S_D / \sqrt{n}}$$

Where

$$S_D = \sqrt{\frac{\sum (D_i - \overline{D})^2}{n - 1}}$$

and t follows a T-distribution with n-1 degrees of freedom. A significant increase in HHS will be claimed if the p-value from this test is less than or equal to 0.05

Secondary Endpoints

The secondary endpoints of range of motion, Oxford Hip Score, and radiographic evaluation and stability assessment will be summarized using descriptive statistics at each follow-up time point indicated in section 4.2. Continuous variable will be summarized using the mean, standard deviation, N, and range. Categorical variable will be summarized frequencies and proportions.

Survival of the implant at 2 years will be calculate using Kaplan-Meier methods. If the implant survives longer than two years, the observation will be censored at two years.

All adverse events, serious adverse events, adverse device effects, and serious adverse device effects will summarized using frequencies and percentages and presented in tabular form.

# 11 Data collection and management

## 11.1 Data collection

Relevant data will be captured on the eCRF. These data which will be transmitted to the sponsor for analysis, will be anonymous and will be identified by a patient number.
As this study is noninterventional, all the data collected will be in accordance with the practice of clinicians implanting Delta Revision acetabular cup.
The Investigator should ensure the accuracy, completeness and timeliness of the data reported in the eCRFs and in all required reports. All data reported should be consistent with the source documents (see section 11.4).
The Sponsor and/or a Sponsor-assigned CRO and directed by the Sponsor will be responsible for data management of this study, including quality checking of the data. Data entered manually will be collected using eCRFs. The sites will be responsible for data entry into the eCRF system. In the event of discrepant data, the Sponsor will request data clarification from the sites, which the sites will resolve electronically in the eCRF system.
eCRFs and correction documentation will be maintained in the EDC system's audit trail. System backups for data stored by the Sponsor and records retention for the study data will be consistent with the Sponsor's standard procedures.
Any queries and items not adequately explained will require additional queries to be raised to the investigator by the Sponsor for clarification/correction. The investigator must ensure that queries are dealt with promptly. All corrections on the eCRF data will be automatically tracked.
At the end of the trial, the Principal Investigator should confirm that the data in CRF are reliable, accurate and complete.

### 11.2 Data management

The eCRFs and patient's questionnaires data transferred/sent from the investigational site to the Sponsor and/or Sponsor- assigned CRO and directed by the Sponsor will be reviewed for completeness, consistency, legibility and protocol compliance.
Data management will be conducted by the Sponsor and/or a Sponsor-assigned CRO and directed by the Sponsor. All data management procedures will be completed in accordance with standard operating procedures of the Sponsor and the Sponsor-assigned CRO.
All data management procedures will be completed in accordance with standard operating procedures for LimaCorporate and the contracted CRO.

### 11.3 Electronic Case Report Forms (eCRF)

All data required in this study is collected on a proper eCRF provided by LimaCorporate. All data documented for each patient is associated to a study ID code composed by study centre code and patient number.
eCRFs are to be completed using a Sponsor-designated EDC system. Sites will receive training and have access to a manual for appropriate eCRF completion. The site personnel, once the training is completed, will receive personal password to not share with other staff members. eCRFs will be submitted electronically to the Sponsor and should be handled in accordance with instructions from the Sponsor.
All eCRFs should be completed by designated, trained site staff. eCRFs should be reviewed by the investigator or a designee.
At the end of the study, the investigator will receive patient data for his or her site in a readable format on a compact disc that must be kept with the study records. Acknowledgment of receipt of the compact disc is required.
Each site is required to have a computer and internet connection available for site entry of clinical data. In order to ensure confidentiality and security of the data, usernames and passwords will be used to restrict system access to authorised personnel only, whether resident within the investigator's sites, LimaCorporate or third parties.
Data entry in the eCRF will be performed by the investigator or by the designated person from his/her staff. It is recommended to complete data entry in the eCRF within maximum 10 working days from the subject's visit.

### 11.4 Source Data Documentation

Study monitors will perform ongoing SDV to confirm that critical protocol data (i.e., source data) entered into the eCRFs by authorized site personnel are accurate, complete, and verifiable from source documents.
Source documents (paper or electronic) are those in which patient data are recorded and documented for the first time. They include, but are not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, patient-reported outcomes, evaluation checklists, radiographical data, intra-operative report, recorded data from automated instruments, copies of transcriptions that are certified after verification as being accurate and complete, microfiche, photographic negatives,

microfilm or magnetic media, X-rays, patient files, and records kept at pharmacies, laboratories, and medico-technical departments involved in a clinical trial.
Source documents that are required to verify the validity and completeness of data entered into the eCRFs must not be obliterated or destroyed and must be retained per the policy for retention of records described in Section 11.5.
To facilitate SDV, the investigators and institutions must provide the Sponsor and/or a Sponsor-assigned CRO with direct access to applicable source documents and reports for trial-related monitoring, Sponsor audits, and IRB/EC review. The site must also allow inspection by applicable health authorities.
The patient must have consented to their medical records being viewed by sponsor authorised personnel and by local, and possibly foreign, competent authorities. This information is included in the informed consent.

### 11.5 Record Archiving and retention

Records and documents pertaining to the conduct of this study, including eCRFs, patient's questionnaires and scores, Informed Consent Forms, laboratory test results, and implant records, must be retained by the Principal Investigator for at least 15 years after completion of the study, or for the length of time required by relevant national or local health authorities, whichever is longer in a secure place. After that period of time, the documents may be destroyed, subject to local regulations.
No records may be disposed of without the written approval of the Sponsor. Written notification should be provided to the Sponsor prior to transferring any records to another party or moving them to another location.

## 12 Ethical Consideration

### 12.1 Compliance with laws and regulations

This study will be conducted in full conformance with the EN ISO 14155:2020 Clinical investigations of medical devices for human subjects – Good Clinical Practice and the principles of the Declaration of Helsinki, 2008, or the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the individual.
This study will also follow the recommendations of the International Ethical Guidelines for Epidemiological Studies, Council for International Organizations of Medical Sciences, 2009 [20].

### 12.2 Informed Consent

The Sponsor's sample Informed Consent Form will be provided to the site after IRB/EC approval. If applicable, it will be provided in a certified translation of the local language.
Prior to participation of a patient in this study, the investigator or designated colleague/clinician will explain the nature and purpose of the data collection to each patient (or patient's legally acceptable representative), in accordance with local policy/guidelines. As all assessments and procedures will be

conducted in accordance with routine medical practice at the site, study participation does not convey any additional risks or burdens for the patient. However, the patient will be provided with information on the benefits and risks of their medical treatment. The patient will be required to provide written informed consent to confirm that they allow their medical data to be collected and analysed. This must be obtained prior to enrolment and any data being entered in the study database. Sufficient time should be allowed to discuss any questions raised by the patient who should be allowed as much time as they need to consider their decision.

The sponsor will provide a sample informed consent form, in language readily understood by the patient. Each patient's original consent form, personally signed and dated by the patient or by the patient's legally acceptable representative, and by the person who conducted the informed consent discussion, will be retained by the investigator.

A copy of each signed Consent Form must be provided to the patient or the patient's legally authorized representative. All signed and dated Consent Forms must remain in the site file and must be available for verification by study monitors at any time.

If during the study important new information becomes available, the consent form will be revised.

Patients must be re-consented to the most current version of the Consent Forms (or to a significant new information/findings addendum in accordance with applicable laws and IRB/EC policy) during their participation in the study. For any updated or revised Consent Forms, the case history or clinical records for each patient shall document the informed consent process and that written informed consent was obtained using the updated/revised Consent Forms for continued participation in the study.

### 12.3 Institutional Review Board or Ethics Committee

This protocol, the Informed Consent Forms, any information to be given to the patient, and relevant supporting information must be submitted to the IRB/EC by the Principal Investigator and Sponsor and reviewed and approved by the IRB/EC before the study is initiated.

In addition, any patient recruitment materials must be approved by the IRB/EC.

The Principal Investigator is responsible for providing written summaries of the status of the study to the IRB/EC annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB/EC.

In addition to the requirements for reporting all AEs/SAEs to the Sponsor, investigators must comply with requirements for reporting AEs/SAEs to the local health authority and IRB/EC.

All data recorded on the eCRF, or used for any other evaluation, is anonymized by the Investigator and codified by an ID number. In all data analysis it will be assured that patient identity will keep anonymous. It is possible that anonymous patient data can be conserved and electronically elaborated for a scientific aim.

### 12.4 Regulatory Approval

As required by applicable local regulations, the Sponsor will ensure all legal regulatory aspects are covered, and obtain approval of the appropriate regulatory bodies, prior to study initiation in regions where an approval is required.

### 12.5 Confidentiality

The Sponsor maintains confidentiality standards by coding each patient enrolled in the study through assignment of a unique patient identification number. This means that patient names are not included in data sets that are transmitted to any Sponsor location. Patient medical information obtained by this study is confidential and may only be disclosed to third parties as permitted by the Informed Consent Form (or separate authorization for use and disclosure of personal health information) signed by the patient, unless permitted or required by law.
Medical information may be given to a patient's personal physician or other appropriate medical personnel responsible for the patient's welfare, for treatment purposes.
Data generated by this study must be available for inspection/audit upon request by representatives of any regulatory health authorities, Sponsor monitors, Sponsor-assigned CRO, and collaborators, and the IRB/EC for each study site, as appropriate.

### 12.6 Financial Disclosure

Investigators will provide the Sponsor with sufficient, accurate financial information in accordance with local regulations to allow the Sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate health authorities.

## 13 Study documentation, monitoring, and administration

### 13.1 Study documentation

The investigator must maintain adequate and accurate records to enable the conduct of the study to be fully documented, including but not limited to the protocol, protocol amendments, Informed Consent Forms, and documentation of IRB/EC and governmental approval. In addition, at the end of the study, the investigator will receive the patient data, which includes an audit trail containing a complete record of all changes to data.

### 13.2 Site Inspections

Site visits will be conducted by the Sponsor or an authorized representative for inspection/audit of study data, patients' medical records, and eCRFs. The investigator will permit national and local health authorities, Sponsor monitors, Sponsor-assigned CRO, and collaborators, and the IRBs/ECs to inspect facilities and records relevant to this study.

### 13.3 Monitoring procedures

The investigator is responsible for the validity of all data collected at the site. The Sponsor is responsible for collecting these data and verifying that the study is conducted in compliance with the protocol, EN ISO 14155:2020 Clinical investigations of medical devices for human subjects – Good Clinical Practice and regulatory requirements.

Sponsor assigned monitors may conduct site visits. The investigator will allow direct access to all relevant files (for all study patients) and for the purpose of verifying entries made in the eCRF, and assist with the monitor's activities, if requested.
Adequate time and space for monitoring visits should be made available by the investigator.
The site must complete the eCRFs within 10 working days of the patient's visit and on an ongoing basis to allow review by the study monitor, both remotely via the internet and during site visits.
Whenever a patient name is revealed on a document required by the sponsor, the name must be blacked out permanently by the site personnel and annotated with the patient number as identification.

### 13.4 Administrative structure

The study will have an eCRF, and will be conducted by a contract research organization (CRO) together with the Sponsor.

### 13.5 Insurance

An insurance policy provides coverage for this study, as reported in the documentation to be submitted and approved by the Ethics Committee.
The name and address of the relevant insurance company, the certificate of insurance, the policy number and the sum insured are filed in the Investigator Site File (ISF).

### 13.6 Publication of data and protection of trade secrets

The results of this study may be published or presented at scientific meetings or any form of scientific communication. If this is foreseen, the investigator agrees to submit all manuscripts or abstracts to the Sponsor prior to submission. This allows the Sponsor to protect proprietary information and to provide comments based on information from other studies that may not yet be available to the investigator.
The Sponsor will comply with the requirements for publication of study results.
Any inventions and resulting patents, improvements, and/or know-how originating from the use of data from this study will become and remain the exclusive and unburdened property of the Sponsor, except where agreed otherwise.

## 13.7 Protocol Amendments

Any protocol amendments will be prepared by the Sponsor. Protocol amendments will be submitted to the IRB/EC and to regulatory authorities in accordance with local regulatory requirements.
Approval must be obtained from the IRB/EC and regulatory authorities (as locally required) before implementation of any changes, except for changes necessary to eliminate an immediate hazard to patients or changes that involve logistical or administrative aspects only (e.g., change in contact information).

# 14 References

[1] W. e. a. Ricci, "Primary Total Hip Replacement With a Noncemented Acetabular Component," *The Journal of Arthroplasty,* vol. 15, no. 2, pp. 146-152, 2000.

[2] M. e. a. Ellenrieder, "Press-fit versus threaded acetabular cups in total hip arthroplasty: Functional and radiological results after five years," *Acta Orthopaedica Belgica,* no. 82, pp. 60-67, 2016.

[3] P. e. a. Aldinger, "Long-term fate of uncemented, threaded acetabular components with smooth surface treatment: minimum 10-year follow-up of two different designs," *Archives of Orthopaedic and Trauma Surgery,* no. 124, p. 469–475, 2004.

[4] A. e. a. Bürkner, "Primary stability of cementless threaded acetabular cups at first implantation and in the case of revision regarding micromotions as indicators," *Biomed Tech,* no. 57, p. 169–174, 2012.

[5] L. e. a. Gala, "Is there still a role for threaded acetabular cups?," *HIP Internetional,* vol. 28, no. 25, pp. 15-20, 2018.

[6] W. Harris, "Traumatic Arthritis of the Hip after Dislocation and Acetabular Fractures: Treatment by Mold Arthroplasty AN END-RESULT STUDY USING A NEW METHOD OF RESULT EVALUATION," *The Journal of the Bone and Joint Surgery,* vol. 51, pp. 737-755, 1969.

[7] A. Nilsdotter and A. Bremander, "https://onlinelibrary.wiley.com/doi/full/10.1002/acr.20549," 07 November 2011. [Online]. [Accessed 04 February 2020].

[8] J. A. Singh, "Clinically important improvement thresholds for Harris Hip Score and its ability to predict revision risk after primary total hip arthroplasty," *BMC Musculoskeletal Disorders,* vol. 17, no. 256, 2016.

[9] P. Söderman, "Is the Harris Hip Score System Useful to Study the Outcome of Total Hip Replacement?," *Clinical Orthopaedics and Related Research,* no. 384, pp. 189-197, 2001.

[10] V. Wylde, I. Learmonth and V. Cavendish, "https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1283979/," 31 October 2005. [Online]. [Accessed 04 February 2020].

[11] D. Murray, R. Fitzpatrick, K. Rogers, H. Pandit, D. Beard, A. Carr and J. Dawson, "The use of the Oxford hip and knee scores.," *J Bone Joint Srg Br.,* pp. 89(8): 1010-4, Aug 2007.

[12] J. DeLee and J. Charnley, "Radiological demarcation of cemented sockets in total hip replacement.," *Clin Orthop Relat Res.,* pp. Nov-Dec;(121):20-32., 1976.

[13] A. Brooker, J. Bowerman, R. Robinson and L. J. Riley, "Ectopic ossification following total hip replacement. Incidence and a method of classification," *J Bone Joint Surg Am.,* pp. Dec;55(8):1629-32., 1973.

[14] T. Gruen, G. McNeice and H. Amstutz, ""Modes of failure" of cemented stem-type femoral components : a radiographic analysis of loosening.," *Clin Orthop Relat Res.,* pp. 141:17-27, 1979.

[15] J. Vanrusselt, "Postoperative radiograph of the hip arthroplasty: what the radiologist should know," *Insights Imaging,* pp. 591-600, 2015.

[16] Mulcahy and Hyojeong, "Current Concepts of Hip Arthroplasty for Radiologists: Part 1, Features and Radiographical Assessment," *American Journal of Roentgenology,* pp. 559-569, 2012.

[17] C. Ranawat, "Correction of Limb-Length Inequality During Total Hip Arthroplasty," *The Journal of Arthroplasty,* 2001.

[18] D. Nunn, "The measurement of migration of the acetabular component of hip prostheses," *Journal of Bone and Joint Surgery,* vol. 71, no. 4, pp. 629-631, 1989.

[19] L. Dorr, "Total hip arthroplasties in patients less than forty-five years old," *Journal of Bone and Joint Surgery - American,* vol. 65, no. 4, pp. 474-479, 1983.

[20] C. f. I. O. (CIOMS), *International Ethical Guidelines for Epidemiological Studies,* Geneva: ISBN 92 9036 081 X, 2009.

[21] F. e. a. Falez, "Current Concepts, Classification, and Results in Short Stem Hip Arthroplasty," *Orthopedics,* vol. 38, no. 3, pp. S6-S13, 2015.

[22] F. e. a. Falez, "Perspectives on metaphyseal conservative stems," *Journal of Orthopaedics and Traumatology,* vol. 9, no. 1, pp. 49-54, 2008.

[23] F. e. a. Giardina, "Short Stems Versus Conventional Stems in Cementless Total Hip Arthroplasty: A Long-Term Registry Study," *The Journal of Arthroplasty,* no. 33, pp. 1794-1799, 2018.

[24] S. e. a. Lidder, "A systematic review of short metaphyseal loading cementless stems in hip arthroplasty," *The Bone & Joint Journal,* no. 101, pp. 502-511, 2019.

[25] M. e. a. Loppini, "Uncemented short stems in primary total hip arthroplasty: the state of the art," *EFORT open reviews,* vol. 3, pp. 149-159, 2018.

[26] M. e. a. Maier, "Cortical hypertrophy with a short, curved uncemented hip stem does not have any clinical impact during early follow-up," *BMC Musculoskeletal Disorders,* vol. 16, no. 371, 2015.

[27] A. e. a. Wiik, "The loading patterns of a short femoral stem in total hip arthroplasty: gait analysis at increasing walking speeds and inclines," *Journal of Orthopaedics and Traumatology,* 2018.

[28] P. Marchetti, "Long-Term Results With Cementless Fitek (or Fitmore) Cups," *The Journal of Arthroplasty,* vol. 20, no. 6, pp. 730-737, 2005.

[29] H. Feyen, "Is the length of the femoral component important in primary total hip replacement?," *The Bone and Joint Journal,* vol. 96, pp. 442-448, 2014.

[30] A. F. Brooker, "Ectopic ossification following total hip replacement. Incidence and a method of classification," *Journal of Bone and Joint Surgery,* vol. 55, no. 8, pp. 1629-1632, 1973.

[31] H. Mulcahy, "Current Concepts of Hip Arthroplasty for Radiologists: Part 2, Revisions and Complications," *American Journal of Roentgenology,* vol. 199, pp. 570-580, 2012.

## Appendix 1 Schedule of Assessments

| | Pre-operative visit [1] | Intraoperative/Discharge visit [2] | Follow-up visit [3] | Survival Follow-up visit [4] |
|---|---|---|---|---|
| Informed Consent [a] | x | | | |
| Inclusion/exclusion criteria | x | | | |
| Demographics [b] | x | | | |
| Medical history [c] | x | | | |
| Vital signs [d] | x | x | | |
| Physical examination | x | x | x | |
| Laboratory evaluations [e] | x | x | | |
| Surgery and Implant data [f] | | x | | |
| Haris Hip Score (HHS) and Range of motion (ROM) | x | x | x | |
| Oxford Hip Score (OHS) | x | x | x | x |
| Radiographical evaluation | x | x | x | |
| Medications [g] | x | x | x | x |
| AE reporting [h] | x | x | x | x |

**1.** The timing of study visits will be in accordance with current local practice at the study site

**2.** Discharge visit: the time from admission date to the discharge will be based according to the current clinical practice and both dates will be entered in the eCRF. Assessments have to be performed in the period between the surgery and discharge.

**3.** Follow-Up 2 months (± 30 days), Follow-Up 6 months (± 60 days), Follow-Up 12 months (± 6 months) and Follow-Up 24 months (± 6 months) since the date of the surgery.

**4.** Survival Follow-Up visit 3 years (± 6 months), 4 years (± 6 months) and, 5 years (± 6 months) since the date of the delta revision acetabular cup implant; the safety and survivorship of the implant will be evaluated. Data collected at each Survival Follow-up visit can be assessed and evaluated by the site staff within a telephone interview and/or a visit at the site according to the clinical practice. A phone interview has to include a brief evaluation of the current status of the hip. The assessment includes some questions about general health status, medical history, feeling and satisfaction about prosthesis. Also the PROM, OHS, has to be performed by phone.
If the Suvival Follow-up visits will be performed at the Hospital, the Investigator has to perform all assessment required during the Follow-up visits.

**a.** Informed consent may be obtained at any time (including prior to the pre-operative visit) but must be obtained prior to the performance of any protocol assessments. All pre-operative evaluations must be completed and reviewed to confirm that patients meet all eligibility criteria before the inclusion.

**b.** Demographic data include age, sex, ethnicity/race, smoking and drinking habits, activity level (e.g. sedentary, normal, intense) and, working status (active worker or retired).

**c.** Medical history includes clinically significant diseases, hip history (including all prior hip therapies and procedures) and, osteoporosis history (including assessment, treatment and nature of the osteoporosis); the affected limb (right or left) is also requested to be collected in the eCRF and to be reported clearly in the medical charts.

**d.** Body height and body weight are mandatory to be recorded only at the pre-operative visit in the eCRF; vital signs (body temperature, pulse, blood pressure) should be obtained and reviewed but are not required to be entered into the eCRF. Significant and severe abnormal vital signs at any time during the course of study should be recorded as AEs or SAEs.

**e.** Routine laboratory evaluations (e.g., hematology and serum chemistry) will be peformed in accordance with current local practice at the study site and will not collected in the eCRF but it is very recommended to store and archive all laboratory reports in the medical charts.

**f.** Surgery data including surgical approach, surgery time and date, intra-operative and immediate post-operative haematocrit measurements.
Implant data for Delta Revision acetabular cup include the type, size, material, batch number and expire date: the label of acetabular cup has to be stored also in the source documents.

## Appendix 1 Schedule of Assessments (cont.)

g. Medications includes e.g., prescription drugs, over-the-counter drugs, herbal/homeopathic remedies, pain medication used by the patient prior to the pre-operative visit.
Medications related to the treatment of SAEs/AEs/ADEs/SADEs/DD are also to be reported during the follow-up period and survival follow-up period.

h. During pre-operative visit, only SAEs considered related to protocol-mandated procedures will be collected.
Patients who withdraw from the study prematurely will be followed for all unresolved AEs/ADEs and/or SAEs/SADEs until their resolution or stabilization, the patient is lost to follow-up or dies, or until it is determined that the study participation is not the cause of the AE/SAE/ADE/SADE, whichever occurs first .

## Appendix 2 Schedule of Radiographical Assessments

| *Assessments* | *X-Ray View* | *Visit* |
|---|---|---|
| Heterotopic Ossification | AP Pelvis [a] | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Acetabular Inclination | AP Pelvis [a] | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Acetabular Anteversion | AP Pelvis [a] | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Acetabular Component Radiolucency | AP Pelvis, Lateral Hip [b] | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Acetabular Component Migration | AP Pelvis | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Dislocation | AP Pelvis | At Discharge, Month 2, Month 6, Month 12, Month 24 |
| Infection | AP Pelvis | At Discharge, Month 2, Month 6, Month 12, Month 24 |

**a.** X-Ray (Antero-Posterior view) has to be performed at preoperative visit, at immediate postoperative and at every follow up visit and uploaded in the eCRF.

**b.** It is very recommended to perform the X-ray (lateral view) and if it is performed to upload in the eCRF and, to archive all related reports in the medical charts.

## Appendix 3 Haris Hip Score (HHS)

*Tick (✓) one box for every question.*

### HARIS HIP SCORE

**Pain**

- □ None or ignores it (44)
- □ Slight, occasional, no compromise in activities (40)
- □ Mild pain, no effect on average activities, rarely moderate pain with unusual activity; may take aspirin (30)
- □ Moderate pain, tolerable but makes concession to pain. Some limitation of ordinary activity or work. May require Occasional pain medication stronger than aspirin (20)
- □ Marked pain, serious limitation of activities (10)
- □ Totally disabled, crippled, pain in bed, bedridden (0)

**Limp**

- □ None (11)
- □ Slight (8)
- □ Moderate (5)
- □ Severe (0)

**Support**

- □ None (11)
- □ Cane for long walks (7)
- □ Cane most of time (5)
- □ One crutch (3)
- □ Two canes (2)
- □ Two crutches or not able to walk (0)

**Distance Walked**

- □ Unlimited (11)
- □ Six blocks (8)
- □ Two or three blocks (5)
- □ Indoors only (2)
- □ Bed and chair only (0)

**Sitting**

- □ Comfortably in ordinary chair for one hour (5)
- □ On a high chair for 30 minutes (3)
- □ Unable to sit comfortably in any chair (0)

**Enter public transportation**

- □ Yes (1)
- □ No (0)

**Patient ID:**

**Examination date** (DD/MMM/YYYY)

**Hip affected** □ Right □ Left

**Stairs**

- □ Normally without using a railing (4)
- □ Normally using a railing (2)
- □ In any manner (1)
- □ Unable to do stairs (0)

**Put on Shoes and Socks**

- □ With ease (4)
- □ With difficulty (2)
- □ Unable (0)

**Absence of Deformity (All yes = 4; Less than 4 =0)**

- □ Less than 30° fixed flexion contracture
- □ Less than 10° fixed abduction
- □ Less than 10° fixed internal rotation in extension
- □ Limb length discrepancy less than 3.2 cm

**Range of Motion** *(*indicates normal)*

- □ Flexion (*140°) _____
- □ Abduction (*40°) _____
- □ Adduction (*40°) _____
- □ External Rotation (*40°) _____
- □ Internal Rotation (*40°) _____

**Range of motion score:** _____

**Total Harris Hip Score:** _____

**Range of Motion scoring guide**

| | |
|---|---|
| 211° - 300° | 5 points |
| 161° - 210° | 4 points |
| 101° - 160° | 3 points |
| 61° - 100 | 2 points |
| 31° - 60° | 1 point |
| 0° - 30° | 0 points |

## Appendix 4 Oxford Hip Score (OHS)

**OXFORD HIP SCORE (OHS)**

**Patient ID:**

**Examination date** _____
(DD/MMM/YYYY)

**Hip affected** □ Right □ Left

Tick (✓) one box for every question.

**1. During the past 4 weeks…**

How would you describe the pain you usually have from your hip?

| None | Very mild | Mild | Moderate | Severe |
|---|---|---|---|---|
| □ | □ | □ | □ | □ |

**2. During the past 4 weeks…**

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. During the past 4 weeks…**

Have you had any trouble getting in and out of a car or using public transport because of your hip?

| No trouble at all | Very little trouble | Moderate trouble | Extreme difficulty | Impossible to do |
|---|---|---|---|---|
| □ | □ | □ | □ | □ |

**4. During the past 4 weeks…**

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. During the past 4 weeks…**

Could you do the household shopping on your own?

| Yes, easily | With little difficulty | With moderate difficulty | With extreme difficulty | No, impossible |
|---|---|---|---|---|
| □ | □ | □ | □ | □ |

**6. During the past 4 weeks…**

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

| No pain/More than 30 minutes | 16 to 30 minutes | 5 to 15 minutes | Around the house only | Not at all/pain severe when walking |
|---|---|---|---|---|
| □ | □ | □ | □ | □ |

**7. During the past 4 weeks…**

Have you been able to climb a flight of stairs?

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

**8. During the past 4 weeks…**

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 painful | Slightly painful | Moderately painful | Very painful | Unbearable |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

**9. During the past 4 weeks…**

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. During the past 4 weeks…**

Have you had any sudden, severe pain - 'shooting', 'stabbing' or 'spasms' - from the affected hip?

| No days | Only 1 or 2 days | Some days | Most days | Every days |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

**11. 1During the past 4 weeks…**

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

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

**12. During the past 4 weeks…**

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 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

***Finally, please check back that you have answered each question.***