Feasibility Assessment Questionnaire

AN OPEN LABEL, MONOCENTRE, OBSERVATIONAL, PROSPECTIVE, LONGITUDINAL COHORT STUDY TO EVALUATE SAFETY, CLINICAL AND RADIOGRAPHIC OUTCOMES OF TOTAL HIP ARTHROPLASTY WITH DELTA REVISION CUP.

Lima Corporate is conducting an open label, monocentre, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision cup in real-life clinical practice

Your site has been identified as one that may have an interest in participating in this study and we would very much appreciate your completion of this questionnaire. If you have an interest in participating, you will be contacted with further information.

Please complete the information below, and return it to the Clinical Department to the following e-mail address: clinical.reserach@limacorporate.com.

Study objectives:

1. Efficay objective: assessment of clinical and radiological outcomes of the DELTA Revision cup

2. Safety objective: incidence, nature and severity of any adverse events.

Study design:

- Observational post-market, monocentre: longitudinal cohort prospective study

Study duration:

- Recruiting: 24 months
- Follow-up: 24 months plus 36 months of Survival Follow-Up visit after the surgery

The study consists of 9 visits:

- Pre-operative visit
- Follow-up (FU) visits: discharge, 2 months, 6 months, 1 year, 2 years after surgery
- Survival Follow-Up (SFU) visits: 3 years, 4 years and 5 years after the surgery

The Study procedures are:

At each Follow-Up (FU) visit, the study procedures are:

- Medical history and demographic data
- Physical examination;
- X-rays as per standard care;
- Radiographic evaluation;
- Clinical assessment: Haris Hip Score (HHS) and Range of Motion (ROM);
- Incidence, nature and severity of any complication and adverse event;
- Survivorship of implant.

At each Survival Follow-Up (SFU) visit, the study procedures are:

- Incidence, nature and severity of any complication and adverse event;
- Survivorship of the implant

Key Inclusion Criteria:

1. Male and/or Female with ≥ 18 years of age;
2. Subjects with the indications for the implantation of DELTA Revision Cup as per indications for use.
3. Adult subjects in whom a decision has already been made to perform hip arthroplasty with DELTA Revision cup.
4. Patient has provided written informed consent for collection of data

Key Exclusion Criteria:

1. Subjects with contraindications for the implantation of DELTA Revision cup contraindications according to the indications for use of DELTA Revision cup.
2. Female patients who are pregnant, nursing, or planning a pregnancy.