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.

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Contact Information
Name of Potential Investigator: Jerzy Bialecki Institution/Hospital: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Address: Księdza Stanisława Konarskiego, 13 City/Country: 05-400 Otwock/Poland Phone number: (0048) 602 - 378640 Email address: Jerzybialecki@pro.onet.pl

Questionnaire:		
1. Do you anticipate potential sub-investigators would be available to assist with subject identification, consenting and enrollment?	☐ Yes	☐ No
2. How many individuals will be performing screening & enrollment activities?		
3. Would you have sufficient and trained staff available to work on the proposed Delta Revision Cup Study?	☐ Yes	☐ No
4. Based on the key inclusion/exclusion criteria noted, how many patients would you expect to enroll per month?	_____ Patients per month	

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Site Profile	
5. How many industry sponsored clinical trials have you conducted in total in the last 5 years?	_____ # of Trials
6 Are there other studies planned to be performed during the next 24 months at your facility, which might conflict with the recruitment in the proposed study?	_____ Number of other studies

Study Design And Requirements		
7. Do you foresee any challenges/restrictions with the subject eligibility criteria?	☐ Yes	☐ No
7a. If you have any concerns about any of the inclusion/exclusion criteria for this study, please provide comments including reasons for your concerns below:		
8. Do you foresee any concerns about the study visits planned by protocol?	☐ Yes	☐ No
8a. If yes, please specify:		
9. Please, describe time-points and evaluations commonly performed as per standard care:		

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Site Capability		
10. Is your site able to enroll a maximum number of 40 subjects in approximately 24 months?	☐ Yes	☐ No
11. Does your site have the ability to perform the x-rays views as planned by protocol and to save the x-rays to media (e.g., DVD/CD/VHS) or to an archive system?	☐ Yes ☐ No ☐ Unknown	
12. Is your site familiar with Electronic Case Report Form (CRF) in clinical trials?	☐ Yes	☐ No

Ethics Committee			
13. Do you use a Local or Central EC or both?	☐ Local	☐ Central	☐ Both
14. Does your site require other departmental or committee review/approval prior to approval from the EC?	☐ Yes	☐ No	
14a. If yes, what is the timeline for review/approval prior to the EC submission?	_____ weeks		
15. Does your local EC require a contract to be signed / executed before EC submission?	☐ Yes	☐ No	
16. How many weeks would you expect from time of first EC submission to first patient enrolled?	_____ weeks ☐ Unknown		

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In case you are not interested, please feel free to recommend other investigators with appropriate clinical research experience who could be potential investigators for this study:

Name: _____ Name: _____

Institution/Hospital: _____ Institution/Hospital: _____

City: _____ City: _____

Phone number: (_____) _____ - _____ Phone number: (_____)

_____ - _____

Email address: _____ Email address: _____

Name: _____

Signature : _____

Date: _____

Thank you very much for your time to complete this questionnaire!