INFORMED CONSENT FORM AND PRIVACY NOTICE FOR DATA PROCESSING

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:	H-34, Delta Revision
SPONSOR:	LimaCorporate S.p.A.
PRINCIPAL INVESTIGATOR	Dr. Jerzy Białecki
SITE NAME:	Hospital: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
SITE ADDRESS:	Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland

Introduction

We would like to invite you to take part in this research study (named also clinical study) on hip joint prosthesis.

In order to allow you to make an informed decision as to whether or not to participate in this research study, this document describes the purpose of the study, your rights and obligations, the necessary procedures in the study and the possible risks and benefits of participating in the study.

We invite you to take all the time you deem appropriate to carefully read this information. You are free to talk to your doctor, nursing staff, family or friends about it before making a decision. If you wish to ask questions, you can contact the doctor of the study for any clarification.

Take your time to decide whether or not you wish to take part.

What is the purpose of the study?

In this clinical study, we want to learn more about the total hip arthroplasty (THA) by doing observations that would normally be done as part of normal tests.

Arthroplasty is a type of orthopaedical intervention that can be applied to different joints of the human body and, consists of a surgical reconstruction or replacement of the damaged elements, in order to restore the correct functioning of the joint itself.

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.

In this clinical study, we aim to find out whether the hip prosthesis will work well and be safe.

While orthopaedical implants have been designed to replicate the shape and natural movement of a healthy hip, no implant designs can completely replicate all the natural movements of a healthy hip. Implant manufacturer and surgeons, however, are continuously trying to improve the design of existing implants to make them even better at replicating the natural movement of a hip.
The purpose of this study is to evaluate the benefits, risks and effects of the implant of the delta revision acetabular cup in patients who requiring a total hip arthroplasty.

What medical device is investigated?

Total Hip arthroplasty (THA) is an artificial joint which replaces the sick hip, eliminating the source of pain effectively and permanently.
The hip prosthesis is regulated by an acetabular cup and a stem, which are connected in the acetabulum and in the femur. A prosthetic head is assembled on the stem which will articulate with the internal surface of the cup.
The fixation of the components is biological, that is entrusted to the penetration of the bone into the porous surface of the elements: it is the so-called cementless prosthesis.
The component of prothesis that will be object of the study is the acetabular cup called Delta Revision.
Delta Revision acetabular cup (figure 1) is intended to replace the natural acetabulum in total hip arthroplasty (THA). Delta Revision acetabular cup are CE marked product, indicating that it is considered to be safe and effective hip replacement system and, used according to the intended use.

Figure 1. Delta Revision acetabular cup

Who is the Sponsor of the study?

The study is promoted by LimaCorporate S.p.A. and it is carried out under the supervision of the study doctor and the staff of the site. LimaCorporate S.p.A provides financial support to cover the costs of the procedures performed during the trial.

Who evaluated and approved this study?

This study has been approved by the reference Ethics Committee of this center, an organization responsible for protecting the rights and safety of patients who participate in research studies.

How many people will participate in the study?

About 49 patients will participate in this study, however the number of planned patients may increase or decrease over time.

What is expected from you? /What are my obligations if I participate in this study?

You were chosen because your doctor has already decided to implant you the Delta Revision acetabular cup. Participating in this study will in no way modify the treatment decided for you and will continue to receive it as per clinical practice at the center, whether you decide to participate in the study or not.

If you decide to take part in this study, you will be required to:

- Respect study appointments and undergo all study evaluations
- If you cannot attend to an appointment, please contact the staff of the study (i.e. the doctor of the study or nurse) as soon as possible to fix a new one.
- Report to the study staff all symptoms, changes of medications, medical visits or hospital admissions that may have occurred
- Inform the study staff if you think you may be pregnant
- Inform study staff if you change your mind about participation at the study

How is research carried out? What will happen if I participate in this research study?

You have been asked to participate in this research study as you are due to undergo a total hip arthroplasty in which the delta revision acetabular cup will be implanted.

If you agree to participate in this clinical study, it is important to understand that these visits are necessary to ensure its quality. Your participation will last for 2 years.

The maximum number of visits is 7 visits, and includes one pre-operative visit (before the hip prosthesis implant), intra-operative visit (at the same day of hip prosthesis implant), discharge visit (after the hip prosthesis), Follow up visits at 2 months, 6 months, 1 year and 2 years after the implant.

Before the hip prosthesis implant, the following tests or procedures should be performed to determine your eligibility for participation in the study. These exams either procedures are be part of your normal medical treatment and, are be performed even if you do not participate in the study. If some have been done recently, they may not have to be repeated.

- Study explanation, reading and signing of this informed consent form;
- Registration of your personal data, including age, gender, ethnicity, smoking and drinking habits, activity level (e.g. sedentary, normal, intense) and, working status (active worker or retired);
- Verification of your medical history and any medicines (including those based on herbs or food supplements) you have been taking or have taken in the past;
- Performing a physical exam that includes weight and height measurement;
- Measurement of vital signs (body temperature, pulse, and blood pressure);
- A radiographic evaluation of the x-rays of the affected hip;
- During the orthopaedic visit, the doctor of the study will ask you to perform a simple functional test to access your mobility and complete two simple questionnaires to assess your health hip status;
- Routine laboratory evaluations (e.g., haematology and serum chemistry).

If pre-operative assessments demonstrate your eligibility to participate in the study, and you are choose to take part, the delta revision acetabular cup will be implanted according to the clinical practice: the surgical procedures such as the method of implant, surgical approach and technique, anaesthesia details, surgery time and intra-operative and immediate post-operative haematocrit measurements are included in your standard medical treatment and the related data will be collected for the purpose of the study.

Before you are discharged to go home, the following tests or procedures will be performed as standard medical practice:

- Performing a physical exam;
- Measurement of vital signs (body temperature, pulse, and blood pressure);
- A radiographic evaluation of the x-rays of the implant;
- The doctor of the study will ask you to perform a simple functional test to access your mobility and complete two simple questionnaires to assess your health hip status;
- Routine laboratory evaluations (e.g., haematology and serum chemistry).

After the discharge, 4 appointments will be planned at the hospital: at 2 months and 6 months, then at 1 year and 2 years after the surgery. At each of these appointments the following procedures will be performed as standard medical treatment:

- Orthopaedic examination and assessment;
- Radiographic evaluation of your implant within the X-ray;
- Completion of 2 simple questionnaires regarding your hip health status and satisfaction's level of your implant.

After the implant of prothesis, you will notify to the study physician of any unexpected changes or unwanted in your health or unwanted effects (adverse events) which could manifest. Your doctor or other qualified clinical staff will monitor possible adverse events continuously. Your doctor will continue to monitor an unresolved side effect until better or stabilize.

LimaCorporate S.p.A. or his representative may contact your doctor for further information case and outcome information (e.g. from discharge letters, specialist reports) in order to perform an independent medical evaluation of the event. An expert external commissioned by LimaCorporate S.p.A. may request (e.g. further information case and outcome information (e.g. from discharge letters, specialist reports), if already taken by the doctor to evaluate the event.

What are the possible benefits and risks in taking part?

Our priority for every participant is his/her well being. There are no individual benefits for you in taking part in this study and the study doctor will carefully monitor your health.

However, the information obtained with this study could help doctors learn more on delta revision acetabular cup implant and total hip arthroplasty in general. This may help us improve the care of patients affected by the disease diagnosed to you in the future.
You will have x-rays taken of your hip joint at each visit. The radiation-related risk (lifetime risk) for the extra doses falls into "Negligible" category.
For safety reasons, the study will not include females who are pregnant, nursing, or planning a pregnancy. If a pregnancy is confirmed during the study the Investigators are required by law to monitor progress of the pregnancy and also to follow up progress of you and your baby after the birth. Please be assured we will not take any x-rays during your pregnancy.
The possible risks and/or discomforts associated with delta revision acetabular cup prosthesis are identical to those for all standard total hip arthroplasty operations. Qualified and experienced clinical staff will monitor carefully any symptoms of discomfort or pain after your surgery as required after every total hip replacement.

What happens if you do not wish to participate in this research?
All participation in research is voluntary. You are free to decide if you want to take part. You will have the same level of care whether they decide to take part or not. This will not affect your care now or in the future. This decision will in no way affect your on-going relationship with your surgeon, nor will it affect your routine care. You can discuss with your surgeon to receive delta revision acetabular cup prosthesis even if you do not take part in this study.

Can I stop participating in the study?
Yes, you can decide to stop it at any time. Your participation in this study is voluntary. You can withdraw from the study at any time without giving a reason. This decision will in no way affect your on-going relationship with your surgeon, nor will it affect your routine care. If you are thinking of withdrawing from study or if you have decided to withdraw, talk to the study doctor who will explain it to you how to proceed and your participation can be stopped in an orderly manner. In any case, you will continue to receive adequate medical treatment for your disease.
Any study information collected up to the time of withdrawal from the study may be used by the study Sponsor, LimaCorporate S.p.A. If you have signed the consent form to allow us to continue to review your medical records after you have withdrawn, information collected may still be used. If you decide to withdraw consent for us to continue to collect any information please advise a member of the research team.

What happens when the research stops?
At the end of the study, your surgeon will continue to follow you up as per standard routine care.
The Sponsor or the regulatory authorities can also decide to suspend or prematurely terminate the study. Your participation may also be terminated if your surgeon finds this to be in your best interest, or if you do not attend the follow-up visits. Regardless of the reason of study end, your surgeon will continue to follow you up as per standard hospital protocol.

What if new information becomes available?
During the study, we will promptly notify you of any new information or study changes that may affect your health or your willingness to continue participation in the study. If this happens, your surgeon will

tell you and discuss whether you should continue in the study. When they are communicated to you such new information, if you agree to continue participating in the study, you will be asked, or your authorized legal representative will be asked, to read another information form and to sign an updated consent form. If you decide not to carry on in the study, your surgeon will arrange for your care as per standard routine practice.
If the Study is stopped for any other reason, the study doctor will tell you and arrange your continuing care.

What are my rights if I participate in this study?
Participation in the study is your choice. You can choose to participate or not. If you decide to participate in this study, you can stop it at any time. Regardless of the decision you make, you will not be penalized in any way and will not lose any of your normal benefits. Stopping the study will not affect your medical treatment.

What if there is a problem?
You will not receive any cash compensation for participating in this research.
If you suffer any injuries or complications as a result of this study, you should contact your surgeons as soon as possible, they will assist you in arranging appropriate medical treatment.
If you have any concerns about any aspect of this study, you should talk to a member of the research team who will do their best to answer your questions.
If you are unhappy and wish to complain formally, you can do this through the hospital complaints procedure. Details can be obtained from the hospital.
LimaCorporate S.p.A. has taken out a liability insurance policy with the CHUBB Insurance Company.. LimaCorporate S.p.A. will renew periodically the policy in order to ensure the coverage for the entire duration of the study.
Your consent to participate in the study does not it implies the waiver of your rights as patient and does not relieve the doctor of the study from his/her responsibility.

What happens to my data?
Your personal data will be treated in accordance with the European data policy regulations 2016/679 of April 27th, 2016 on the protection of individuals with regards to processing of personal data (GDPR) and with regards to the data policy of the national laws for data protection, as well as the general data protection regulations.
Data controller are the hospital where the research is carried out and LimaCorporate, each for the part of its competence.
You will find all the information relating to how your data will be treated in the "Privacy notice for personal data processing " below.
Your medical records and the data collected for the study will be looked at by authorised people from the company organising and sponsoring the research. They may also be looked at by authorised people, such as regulatory authorities, to check that the study is being carried out properly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.
All information which is collected/leaves the hospital about you during the course of the study will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

At the beginning of the study, an identification number will be assigned on all documentation, in order to guarantee the anonymity. Information may be recorded on a computer database by the company sponsoring the study, however, this will not contain your name, only your identification number, and confidentiality will be maintained at all times. The investigators and company sponsoring the study will not reveal your identity in any publication resulting from this study.
Data will be pseudonymised (name, address or information allowing your identification removed and replaced with an identification code) so that you cannot be recognised anymore. The correspondence table where the code is linked to your name will be kept by the Principal Investigator at the site where the research is carried out. The principal investigator and his authorized study staff team will know your identity. Also, your medical notes and data collected during the study may be looked at by individuals from regulatory authorities or employed by the sponsor where it is relevant to your taking part in this research.
The coded personal data of this study may be forwarded to and processed by authorized recipients outside Europe, where the European General Data Protection Regulation is not valid or where privacy standards may be lower than in the EU (such as the US) for activities related to data analysis and review (e.g. statistical analysis, radiographic evaluation, etc.) or upon request of the Regulatory Authorities. In case of processing outside of Europe, the coded personal data will be adequately protected.
Upon completion of the study, data will be stored at the hospital where the study carried out and the sponsor for up to 15 years. The results of this study may be published in relevant scientific journals and presented at conferences and meetings. No personal identifiable data will be disclosed in any publication.

Who can answer my study questions?
You may ask any questions you like at any time about your rights as a participant in this clinical study or about the clinical study itself. The Principal Investigator or a member of the study team will be available to discuss these issues with you. You can contact your study doctor if you have any questions or concerns about the study, if would like to withdraw your consent to participate in the study or if you believe you have suffered damage due to your participation in the study. Contact the doctor of the study on:
Dr. Jerzy Białecki
Telephone number: 0048602378640
Email address: jerzybialecki@pro.onet.pl
Hospital: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Address: Księdza Stanisława Konarskiego, 13
City: 05-400 Otwock
Country: Poland
For questions about your processing of personal data you can contact Dariusz Skowera, iod@spskgruca.pl or sekretariat@spskgruca.pl *(Data Protection Officer DPO of the Hospital)* at the Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP in which the study is carried out
or
Data Protection Officer of the Sponsor and may be contacted at: dpo@enovis.com.

Signature - Consent for participation in the study

I, the undersigned, confirm that I have received a copy of all the pages of this form after signing it and putting the date on it. I have read the document or it has been read to me, I understand it and I have

received answers to the questions I have asked. I voluntary agree to participate in the research study described above and I authorize the study center to use and disclose (share) my health information in the manner described in this informed consent form.

Name and surname of the patient (in block letters)

If applicable - Name and surname of the representative authorized legal counsel of the patient (block letters)

Signature of the patient or legal authorized representative

Date

I, the undersigned, have fully explained this informed consent to the afore mentioned patient and/or his/her legally authorized representative.

Name and surname of the person who led the discussion on informed consent (block letters)

Signature of the person who led the discussion on informed consent

Date

Name and surname of the witness (block letters)*

Signature of the witness

Date

*If the Principal investigator or the Ethics Committee believes it necessary to sign a witness (in accordance with the ICH guidelines and good clinical practice [E6], 4.8.9).

Signature - General Practitioner information

Your own General Practitioner (GP) may be informed about your participation in the study. This is customary and is in the interest of your safety. Hence, your GP may inform us of any new medical information relevant to your hip prosthesis (i.e. in comfort, adverse event). We may also inform him of any relevant unresolved event at the time you complete the study. You may select if you wish or not the GP to be informed on your participation in the study. This correspondence will help to propose you a closer follow-up. You may select if you wish or not the GP to be informed on your participation in the study:

☐ I agreed to inform my GP ☐ I do not agree to inform my GP

Name and surname of the patient (in block letters)

If applicable - Name and surname of the representative authorized legal counsel of the patient (block letters)

Signature of the patient or legal authorized representative

Date

Part to be completed in the event of signing by a witness

Name and surname of the witness (block letters)

Signature of the witness

Date

Signature - Privacy notice for data processing

Data controllers and related purposes

The hospital where the research is carried out, Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP, and LimaCorporate S.p.A. (33038 Villanova di San Daniele (UD) - Via Nazionale, 52, Italy), who sponsors the study, are the data controllers each for the part of its competence according to responsibilities foreseen by the applicable regulations.

Your personal data will be treated in accordance with the data policy regulations 2016/679 of April 27th, 2016 on the protection of individuals with regards to processing of personal data (GDPR) and with regards to the data policy of the national laws for data protection, as well as the general data protection regulations.

In case you need any information on the processing of personal data you can contact Dariusz Skowera, iod@spskgruca.pl or sekretariat@spskgruca.pl at the Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Hospital or the Data Protection Officer of the Sponsor, Ms. Elena Bianchi at dpo@enovis.com.

In the context of this study, data will be stored and transmitted to the sponsor. All information which is collected and leaves the hospital about you during the course of the study will be kept strictly confidential. Data will be pseudonymised (name, address or information allowing your identification removed and replaced with an identification code) so that you cannot be recognised anymore. The correspondence table where the code is linked to your name will be kept by the Principal Investigator at the Hospital where the study is carried out. The principal investigator and his authorized study staff team will know your identity. Also, your medical notes and data collected during the study may be looked at by individuals from regulatory authorities or employed by the sponsor where it is relevant to your taking part in this research.

The coded personal data of this study may be forwarded to and processed by authorized recipients outside Europe, where the European General Data Protection Regulation is not valid or where privacy standards may be lower than in the EU (such as the US) for activities related to data analysis and review (e.g. statistical analysis, radiographic evaluation, etc.) or upon request of the Regulatory Authorities. In case of processing outside of Europe, the coded personal data will be adequately protected.

Type of data processed

The doctor who will follow you into the study will identify you with a code: the data concerning you, collected in the course of the Study, with the exception of your name, will be sent to LimaCorporate, recorded, processed and stored together with this code, your year of birth, sex, your weight and your height and all information relating to your health, as specified above in the Informed Consent Form for participation in the study, which was provided to you. Only the doctor and the subjects authorized by in charge of the study within the hospital where the research study is carried out will be able to link this code to your name.

Your data will be processed for the following purposes:

- ensure correct and complete implementation of the study, and scientific and statistical research activities ad it related,
- ensure the correct fulfilment of surveillance obligations, as required by law;

Method of processing

The data, processed using electronic tools, will be disclosed only in strictly anonymous and aggregated form, for example through scientific publications, statistics and scientific conferences. In accordance with the legislation on clinical trials, the staff of the Sponsor or of the external companies that perform the monitoring and verification of the study on behalf of the Sponsor, the Ethics Committee, the national and foreign health authorities could know your data, also contained in your original clinical documentation, in ways that guarantee the confidentiality of your identity.
Your pseudonymised data will be kept for a period of 15 years from the end of study, at LimaCorporate S.p.A. (33038 Villanova di San Daniele (UD) - Via Nazionale, 52, Italy).
Furthermore, prior your specific consent, if you agree to the secondary use of the data collected for further research as describe in the section "Secondary use of data", which in any case does not affect your participation in the study, your data could be used by LimaCorporate for future research to improve and better understand the medical device, or to develop new therapies for conditions such as yours, medical conferences, and training for physicians and other medical personnel.

Rights

You may exercise your rights according to the articles 16, 18, 20 of the European Regulation 679/2016 (European General Data Protection Regulation, GDPR) and that is: access to your personal data, rectification, opposition for legitimate reasons, portability (e.g. access your personal data, integrate them, update them, correct them, oppose their treatment for legitimate reasons, etc.) by contacting the study doctor of the hospital directly

Dr. Jerzy Białecki
Telephone number: 0048602378640
Email address: jerzybialecki@pro.onet.pl
Hospital: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Address: Księdza Stanisława Konarskiego, 13
City: 05-400 Otwock
Country: Poland

Or the Sponsor of the study (in this case with indication of your patient code) at dpo@enovis.com.

For any complaint, you can contact the Guarantor Authority for the protection of personal data (contacts at www.uodo.gov.pl): the Personal Data Protection Office can be contacted at 606-950-000 or kancelaria@uodo.gov.pl

It is your right to object at any time your participation in the study without providing any justification, withdrawing consent to the processing of data. Furthermore, no further data concerning you will be collected, without prejudice to the use of those possibly already collected to determine the results of the research.

By signing this form, I am aware about the processing of my personal data and their transfer in countries within and outside the European Union, as well as the communication to the subjects indicated above,

for the purposes of the research within the limits and in the manner indicated in the information above that was provided to me with this document (Privacy notice for data processing).

Name and surname of the patient (in block letters)

If applicable - Name and surname of the representative authorized legal counsel of the patient (block letters)

Signature of the patient or legal authorized representative

Date

Part to be completed in the event of signing by a witness

Name and surname of the witness (block letters)

Signature of the witness

Date

Signature - Secondary use of data

LimaCorporate would like to ask for your permission to the secondary use of your information and results obtained from this study for future research to improve these medical devices, or to develop new therapies for conditions such as yours, medical conferences, and training for physicians and other medical personnel.

☐ I voluntary agree to the secondary use of the data collected for further research as describe above

☐ I voluntary do not agree the secondary use of the data collected for further research as describe above

Name and surname of the patient (in block letters)

If applicable - Name and surname of the representative authorized legal counsel of the patient (block letters)

Signature of the patient or legal authorized representative

Date

Part to be completed in the event of signing by a witness

Name and surname of the witness (block letters)

Signature of the witness

Date