Serious Adverse Events Report

This form is to be completed within 24 hours of becoming aware of the SAE

REPORT INFORMATION	
Report type	☐ Initial ☐ Follow-up ☐ Final ☐ Initial & Final
Report Date	(dd/mm/yyyy)
Date of Onset	(dd/mm/yyyy)
Date of Study Team Aware	(dd/mm/yyyy)
Time team became aware (24 hr clock)	hh/mm

CLINICAL STUDY INFORMATION	
Title of clinical study	**Delta Revision CUP**
Protocol ID	**H-34**

INFORMATION ON THE STUDY SITE	
Name of the healthcare facility	
Name of the Principal Investigator	
Address Postal code City Country	Phone Fax E-mail

MEDICAL DEVICE INFORMATION	
Name of the medical device	
Components	
Indication(s) for use	

INFORMATION ON THE CLINICAL STUDY SUBJECT	
ID number of study subject	
Age	
Gender	☐ Female ☐ Male
Attribution within the clinical investigation	☐ Treatment group ☐ Control group (if any) ☐ Unknown. Remarks ....

CONCOMITANT DRUG(S) AND HISTORY	
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical	

history	
Current clinical status	

EVENT INFORMATION	
Adverse Event (diagnosis, if known, or signs/symptoms)	
Admission date (dd/mm/yyyy)	
Discharge date (dd/mm/yyyy)	
Event narrative:	
Classification of the adverse event	☐ Serious health threat to several study subjects ☐ Single serious criteria: – Death – Light threatening illness & Injury – Hospitalisation or prolongation of hospitalisation – Permanent impairment of body structure of body function – Medical or surgical intervention required to prevent any of the above – Led to foetal distress, foetal death, or congenital abnormality or birth defect – Other (maybe protocol specific)-Specify: _____ ☐ Near incident (serious incident avoided due to a fortunate circumstances) ☐ other
Outcome of the event	☐ Recovered (Date of recovery (dd/mm/yyyy) ☐ Recovered with sequalae (Date of recovery (dd/mm/yyyy) ☐ Ongoing- Details:_____ ☐ Fatal Date of Death: ☐ Unknown at present
Cause of Death:	
Cause of death obtained from: *(tick one)*	
☐ working diagnosis	☐ cononer's inquest ☐ Death Certificate
Supporting documentation to be supplied with SAE/SADE	

Severity	☐Mild ☐ Moderate ☐ Severe
Causality: relationship to medical device	☐ Causal relationship (related) ☐ Probable ☐ Possible ☐ Not Related
Causality: relationship to procedure	☐ Causal relationship (related) ☐ Probable ☐ Possible ☐ Not Related
Expectedness ***(the assessment of expectedness must be based on the information contained in the approved Investigator Brochure and/or Analysis Report and/or Protocol)***	
☐ Anticipated	☐ Unanticipated
If the event is related and unanticipated it is and Unexpected Serious Adverse Device Event (USADE) and requires expedited reporting. Inform the Sponsor immediately. Email: clinical.research@limacorporate.com Tel. Number +39 0432 945 511	
Was the event related to a protocol violation ?	
☐ Yes	☐ No
Was the subject withdrawn due to this event?	
☐ Yes	☐ Yes
Action taken regarding study device ☐ Pharmacological ☐ Not pharmacological ☐Both ☐ Device Permanently removed Date: ☐ Other- provide details_____ Detailed Treatment given:_____ ☐ None ☐ Unknown at time of report ☐ Not applicable	

Attachments		
Relevant medical history	☐	
Relevant medical records	☐	
Laboratory Results	☐	
Imaging Methods (e.g. X-ray, CT-scan)	☐	
Other (please specify)	☐	

INFORMATION ON SUBMITTER OF THE REPORT	
Submitter	☐ Principal Investigator ☐ Other (identify the role of the delegated person by the Principal Investigator)_____
Name of submitter Signature of submitter Date:	_____ _____
Address Postal code City Country	Phone Fax E-mail