Serious Adverse Event Report

Event 20-Oct-2021 - report of 04-Jul-2022 - 13:56 UTC, revision 2

Initial Report Date	03-Feb-2022
Date of this report	04-Jul-2022
Investigator/reporter	Julia Macias
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	5
Event onset	20-Oct-2021
Report type	Initial
Date of Study Team Aware	20-Oct-2021 00:00
Title of clinical study	H-34 - DELTA Revision study
Name of the healthcare facility	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Name of the Principal Investigator	Jerzy Białecki
Name of the medical device involved	Revision Hip /Anca
Components involved	Stem17mm/200mm
ID number of study subject	101 - 5
Age	76
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

5 Report

Adverse Event (diagnosis, if known, or signs/symptoms)	Intraoperative fracture of femur shaft
Event narrative	The femur shaft was weakened beacuse of previous use of metal loop;
Admission date (dd-mmm-yyyy)	18-Oct-2021
Discharge date (dd-mmm-yyyy)	27-Oct-2021
Classification of the adverse event	Hospitalization
Outcome of the event	Recovered 22-Nov-2021
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical histor	The femur shaft was weakened beacuse of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofit;
Current clinical status	On the first control visit 22 Nov 2021 patient is walking with 2 crutches;
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	Anticipated
Action taken	Other intraoperative reduction and fixation of the fracture
Was the device permanently removed?	No
Detailed treatment	
Relevant medical history	None
Relevant medical records	None

5 Report

Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	None
Other (please specify)	None
Submitter	Investigator
Name of submitter	Julia Macias

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/5
Form: Adverse event

Date	Time	User	Values
04-Jul-2022	13:56:06 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Outcome of the event: from **Ongoing** to **Recovered** - Outcome / Recovered date: from **<empty>** to **22-Nov-2021** - Notes: from **<empty>** to **<empty>**
03-Feb-2022	09:24:51 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value **Initial** - Initial Report Date: value **03-Feb-2022** - Report Date: value **03-Feb-2022** - Date of Study Team Aware: value **20-Oct-2021** - Time team became aware (24 hr clock): value **00:00:00** - Title of clinical study: value **DELTA Revision study** - Protocol ID: value **H-34** - Name of the healthcare facility:

			value **Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP** - Name of the Principal Investigator: value **Jerzy Białecki** - Name of the medical device involved: value **Revision Hip /Anca** - IsMedicalDeviceNameNA: value **False** - Components involved: value **Stem17mm/200mm** - IsMedicalDeviceComponentsNA: value **False** - ID number of study subject: value **101 - 5** - Age: value **76** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Intraoperative fracture of femur shaft** - Event narrative: value **The femur shaft was weakened beacuse of previous use of metal loop;** - Admission date (dd-mmm-yyyy): value **18-Oct-2021** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **27-Oct-2021** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event:

			value **Hospitalization** - Outcome of the event: value **Ongoing** - Outcome / Recovered date: value **<empty>** - Outcome / Recovered with sequalae date: value **<empty>** - Outcome / Fatal date: value **<empty>** - Relevant concomitant drugs and date of administration: value **<empty>** - Detail all possible and suspected causes including relevant medical history: value **The femur shaft was weakened beacuse of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofit;** - Current clinical status: value **On the first control visit 22 Nov 2021 patient is walking with 2 crutches;** - Severity: value **Severe** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **Anticipated** - Action taken: value **Other** - Was the device permanently removed?: value **False** - If yes, then please specify date of removal surgery: value **<empty>** - Action taken regarding study device / Other: value **intraoperative reduction and fixation of the fracture** - Detailed treatment:

			value **<empty>** - Attachments / Relevant medical history: value **False** - Attachments / Relevant medical records: value **False** - Attachments / Laboratory Results: value **False** - Attachments / Imaging Methods (e.g., X-ray, CT-scan): value **False** - Attachments / Other: value **False** - Attachments / Other / Specify: value **<empty>** - Submitter: value **Investigator** - Name of submitter: value **Julia Macias** - Event Onset: value **20-Oct-2021** - Serious Event: value **True** - Notes: value **<empty>**