Serious Adverse Event Report

Event 04-Jun-2022 - report of 14-Sep-2022 - 11:40 UTC, revision 7

Initial Report Date	17-Jun-2022
Date of this report	14-Sep-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	14
Event onset	04-Jun-2022
Report type	Initial
Date of Study Team Aware	05-Jun-2022 08:00
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	Delta Revision cup/Modulus-R
Components involved	cup/stem
ID number of study subject	101 - 14
Age	40
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)	Dislocation of left hip
Event narrative	at night, when standing up of bed she fell pain
Admission date (dd-mmm-yyyy)	04-Jun-2022
Discharge date (dd-mmm-yyyy)	13-Jun-2022
Classification of the adverse event	InterventionRequired
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	-
Detail all possible and suspected causes including relevant medical histor	Suspected cause is initial migration of the cup.
Current clinical status	Reoperation is planned.
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	Possible
Expectedness	Anticipated
Action taken	NotPharmacological
Was the device permanently removed?	No
Detailed treatment	13.06.2022- reposition of the hip;
Relevant medical history	None
Relevant medical records	None

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

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/14
Form: Adverse event

Date	Time	User	Values
14-Sep-2022	11:40:30 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Causality: relationship to study medical device: from **Probable** to **Not Related**
30-Jul-2022	12:47:51 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Action taken regarding study device / Other: from **<empty>** to **<empty>** - Notes: from **<empty>** to **<empty>**
17-Jun-2022	11:33:23 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment deleted: **31.jpg**
17-Jun-2022	11:33:17 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: **32.jpg**
17-Jun-2022	11:33:10 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: **31.jpg**
17-Jun-2022	11:33:06 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: **2.jpg**
17-Jun-2022	11:23:09 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value **Initial** - Initial Report Date: value **17-Jun-2022** - Report Date: value **17-Jun-2022** - Date of Study Team Aware:

			value **05-Jun-2022** - Time team became aware (24 hr clock): value **08:00:00** - 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 **Delta Revision cup/Modulus-R** - IsMedicalDeviceNameNA: value **False** - Components involved: value **cup/stem** - IsMedicalDeviceComponentsNA: value **False** - ID number of study subject: value **101 - 14** - Age: value **40** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Dislocation of left hip** - Event narrative: value **at night, when standing up of bed she fell pain** - Admission date (dd-mmm-yyyy): value **04-Jun-2022**

			- IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **13-Jun-2022** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event: value **InterventionRequired** - 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 **-** - Detail all possible and suspected causes including relevant medical history: value **Suspected cause is initial migration of the cup.** - Current clinical status: value **Reoperation is planned.** - Severity: value **Severe** - Causality: relationship to study medical device: value **Probable** - Causality: relationship to study procedure: value **Possible** - Expectedness: value **Anticipated** - Action taken: value **NotPharmacological** - 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 **<empty>** - Detailed treatment: value **13.06.2022- reposition of the hip;** - 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 **True** - Attachments / Other: value **False** - Attachments / Other / Specify: value **<empty>** - Submitter: value **Investigator** - Name of submitter: value **Julia Macias** - Event Onset: value **04-Jun-2022** - Serious Event: value **True** - Id: value **954** - Notes: value **<empty>**