1 Report

Serious Adverse Event Report

Event 30-Nov-2021 - report of 21-Jul-2023 - 14:43 UTC, revision 2

Initial Report Date	21-Jul-2023
Date of this report	21-Jul-2023
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	1
Event onset	30-Nov-2021
Report type	InitialAndFinal
Date of Study Team Aware	30-Nov-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	
Components involved	
ID number of study subject	101 - 1
Age	48
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

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Adverse Event (diagnosis, if known, or signs/symptoms)	Surgery of the controlateral side.
Event narrative	Total hip replacement of rigt hip.
Admission date (dd-mmm-yyyy)	29-Nov-2021
Discharge date (dd-mmm-yyyy)	03-Dec-2021
Classification of the adverse event	Hospitalization
Outcome of the event	Recovered
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical histor	
Current clinical status	
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	Anticipated
Action taken	None
Was the device permanently removed?	No
Detailed treatment	
Relevant medical history	None
Relevant medical records	None

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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: 101/1
Form: Adverse event

Date	Time	User	Values
21-Jul-2023	14:43:24 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Action taken regarding study device / Other: from **<empty>** to **<empty>** - Event Onset: from **30-Nov-2022** to **30-Nov-2021** - Notes: from **<empty>** to **<empty>**
21-Jul-2023	14:42:33 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value **InitialAndFinal** - Initial Report Date: value **21-Jul-2023** - Report Date: value **21-Jul-2023** - Date of Study Team Aware: value **30-Nov-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 **<empty>** - IsMedicalDeviceNameNA: value **False** - Components involved: value **<empty>** - IsMedicalDeviceComponentsNA: value **False** - ID number of study subject: value **101 - 1** - Age: value **48** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Surgery of the controlateral side.** - Event narrative: value **Total hip replacement of rigt hip.** - Admission date (dd-mmm-yyyy): value **29-Nov-2021** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **03-Dec-2021** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event: value **Hospitalization**

			- Outcome of the event: value **Recovered** - 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 **<empty>** - Current clinical status: value **<empty>** - Severity: value **Moderate** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **Anticipated** - Action taken: value **None** - 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 **<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 **30-Nov-2022** - Serious Event: value **True** - Id: value **1077** - Notes: value **<empty>**