1 Report

Serious Adverse Event Report

Event 30-Nov-2021 - report of 30-Nov-2023 - 15:38 UTC, revision 6

Initial Report Date	21-Jul-2023
Date of this report	30-Nov-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	N/A
Components involved	N/A
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 03-Jan-2022
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
30-Nov-2023	15:38:38 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Name of the medical device involved: from **<empty>** to **<empty>** - Components involved: from **<empty>** to **<empty>** - Outcome / Recovered date: from **<empty>** to **03-Jan-2022**
30-Nov-2023	15:15:13 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Name of the medical device involved: from **<empty>** to **<empty>** - .IsMedicalDeviceNameNA: from **False** to **True** - Components involved: from **<empty>** to **<empty>** - .IsMedicalDeviceComponentsNA: from **False** to **True**
21-Jul-2023	14:44:54 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: **rtg2.jpg**

21-Jul-2023	14:44:45 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: **rtg1.jpg**
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>**