1 Report

Serious Adverse Event Report

Event 30-Nov-2021 - report of 30-Nov-2023 - 15:39 UTC, revision 7

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	NA
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

Laboratory Results	None

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/1
Form: Adverse event

Date	Time	User	Values

30-Nov-2023	15:39:24 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Expectedness:
			   from **Anticipated**
			   to **N/A**

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**

30-Nov-2023 15:39:26 (UTC)

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>**