

1 Report

Serious Adverse Event Report

Event 30-Nov-2022 - report of 21-Jul-2023 - 14:42 UTC, revision 1

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-2022

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 Bialecki

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

1 Report

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

Clinical Study: H-34 DELTA Revision study

Patient ID: 101/1

Form: Adverse event

Date	Time	User	Values
21-Jul-2023	14:42:33 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none">- 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 Biłdecki- Name of the medical device involved: value <empty>- IsMedicalDeviceNameNA: value False- Components involved:

			<ul style="list-style-type: none"> 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:
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			<ul style="list-style-type: none"> 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:
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			<div>value <empty></div> <div>- Submitter: value Investigator</div> <div>- Name of submitter: value Julia Macias</div> <div>- Event Onset: value 30-Nov-2022</div> <div>- Serious Event: value True</div> <div>- Id: value 1077</div> <div>- Notes: value <empty></div>
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