

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

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Adverse Event (diagnosis, if known, or signs/symptoms)	Surgery of the contralateral side.
Event narrative	Total hip replacement of right 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 history	
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 Białecki- Name of the medical device involved: value <empty>- IsMedicalDeviceNameNA: value False- Components involved:

		<p>value <empty></p> <ul style="list-style-type: none">- 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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		<p>value <empty></p> <ul style="list-style-type: none">- 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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			<p>value <empty></p> <ul style="list-style-type: none">- 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>
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