

Serious Adverse Event Report

Event 04-Jun-2022 - report of 14-Sep-2022 - 11:41 UTC, revision 8

Initial Report Date	17-Jun-2022
Date of this report	14-Sep-2022
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	14
Event onset	04-Jun-2022
Report type	Initial
Date of Study Team Aware	05-Jun-2022 08:00
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	Delta Revision cup/Modulus-R
Components involved	cup/stem
ID number of study subject	101 - 14
Age	40
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

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Adverse Event (diagnosis, if known, or signs/symptoms)	Dislocation of left hip
Event narrative	at night, when standing up of bed she felt pain
Admission date (dd-mmm-yyyy)	04-Jun-2022
Discharge date (dd-mmm-yyyy)	13-Jun-2022
Classification of the adverse event	InterventionRequired
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	-
Detail all possible and suspected causes including relevant medical history	Suspected cause is initial migration of the cup.
Current clinical status	Reoperation is planned.
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	Possible
Expectedness	Anticipated
Action taken	NotPharmacological
Was the device permanently removed?	No
Detailed treatment	13.06.2022- reposition of the hip;
Relevant medical history	None
Relevant medical records	None

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Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	Available
Other (please specify)	None
Submitter	Investigator
Name of submitter	Julia Macias

Clinical Study: H-34 DELTA Revision study

Patient ID: 101/14

Form: Adverse event

Date	Time	User	Values
14-Sep-2022	11:41:35 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Event narrative: from at night, when standing up of bed she fell pain to at night, when standing up of bed she felt pain
14-Sep-2022	11:40:30 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Causality: relationship to study medical device: from Probable to Not Related
30-Jul-2022	12:47:51 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Action taken regarding study device / Other: from <empty> to <empty> - Notes: from <empty> to <empty>
17-Jun-2022	11:33:23 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment deleted: 31.jpg
17-Jun-2022	11:33:17 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: 32.jpg
17-Jun-2022	11:33:10 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: 31.jpg
17-Jun-2022	11:33:06 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Attachment added: 2.jpg
17-Jun-2022	11:23:09 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value Initial - Initial Report Date: value 17-Jun-2022

		<ul style="list-style-type: none">- Report Date: value 17-Jun-2022- Date of Study Team Aware: value 05-Jun-2022- Time team became aware (24 hr clock): value 08:00:00- 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 Delta Revision cup/Modulus-R- IsMedicalDeviceNameNA: value False- Components involved: value cup/stem- IsMedicalDeviceComponentsNA: value False- ID number of study subject: value 101 - 14- Age: value 40- Gender: value Female- Attribution within the clinical investigation: value TreatmentGroup- Adverse Event (diagnosis, if known, or signs/symptoms): value Dislocation of left hip- Event narrative:
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			<p>value at night, when standing up of bed she fell pain</p> <ul style="list-style-type: none">- Admission date (dd-mmm-yyyy): value 04-Jun-2022- IsEventInformationAdmissionDateNA: value False- Discharge date (dd-mmm-yyyy): value 13-Jun-2022- IsEventInformationDischargeDateNA: value False- Classification of the adverse event: value InterventionRequired- Outcome of the event: value Ongoing- 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 -- Detail all possible and suspected causes including relevant medical history: value Suspected cause is initial migration of the cup.- Current clinical status: value Reoperation is planned.- Severity: value Severe- Causality: relationship to study medical device: value Probable- Causality: relationship to study procedure: value Possible- Expectedness: value Anticipated- Action taken:
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		<p>value NotPharmacological</p> <ul style="list-style-type: 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 13.06.2022- reposition of the hip;- 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 True- Attachments / Other: value False- Attachments / Other / Specify: value <empty>- Submitter: value Investigator- Name of submitter: value Julia Macias- Event Onset: value 04-Jun-2022- Serious Event: value True- Id: value 954- Notes: value <empty>
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