

Serious Adverse Event Report

Event 24-Apr-2023 - report of 29-Dec-2023 - 14:02 UTC, revision 4

Initial Report Date	17-May-2023
Date of this report	29-Dec-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	17
Event onset	24-Apr-2023
Report type	Initial
Date of Study Team Aware	26-Apr-2023 10:38
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
Components involved	Delta revision cup
ID number of study subject	101 - 17
Age	75
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

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Adverse Event (diagnosis, if known, or signs/symptoms)	Periprosthetic fracture- fracture of right pubis bone
Event narrative	A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip.
Admission date (dd-mmm-yyyy)	26-Apr-2023
Discharge date (dd-mmm-yyyy)	28-Apr-2023
Classification of the adverse event	Hospitalization
Outcome of the event	Recovered 04-Sep-2023
Relevant concomitant drugs and date of administration	No.
Detail all possible and suspected causes including relevant medical history	There is a possibility that the connection of screws with the acetabulum is stiff enough to cause a fracture of the pubis bone.
Current clinical status	Under the observation.
Severity	Moderate
Causality: relationship to study medical device	Probable
Causality: relationship to study procedure	CausalRelationship
Expectedness	Unanticipated
Action taken	NotPharmacological
Was the device permanently removed?	No
Detailed treatment	Diagnostics of periprosthetic fracture- computed tomography
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: 101/17

Form: Adverse event

Date	Time	User	Values
29-Dec-2023	14:02:45 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> - Outcome of the event: from Ongoing to Recovered - Outcome / Recovered date: from <empty> to 04-Sep-2023
29-Dec-2023	14:00:21 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> - Attachment added: rtg.jpg
17-May-2023	12:15:16 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> - .ReportType: from Follow-up to Initial - Event narrative: from A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip, without meta features in the fracture area. On the wall of the chest, there is a change after the mastectomy , which requires urgent oncological consultation. to A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip. - Causality: relationship to study procedure: from Not Related to Causal relationship (related) - Action taken regarding study device / Other: from <empty> to <empty>

			<ul style="list-style-type: none"> - Detailed treatment: from Diagnostics- computed tomography to Diagnostics of periprosthetic fracture- computed tomography - Notes: from <empty> to <empty>
17-May-2023	10:23:48 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> - ReportType: value FollowUp - Initial Report Date: value 17-May-2023 - Report Date: value 17-May-2023 - Date of Study Team Aware: value 26-Apr-2023 - Time team became aware (24 hr clock): value 10:38:00 - 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 Bięcki - Name of the medical device involved: value Delta revision cup - IsMedicalDeviceNameNA: value False - Components involved: value Delta revision cup - IsMedicalDeviceComponentsNA: value False - ID number of study subject:

			<p>value 101 - 17</p> <ul style="list-style-type: none">- Age: value 75- Gender: value Female- Attribution within the clinical investigation: value TreatmentGroup- Adverse Event (diagnosis, if known, or signs/symptoms): value Periprosthetic fracture- fracture of right pubis bone- Event narrative: value A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip, without meta features in the fracture area. On the wall of the chest, there is a change after the mastectomy , which requires urgent oncological consultation.- Admission date (dd-mmm-yyyy): value 26-Apr-2023- IsEventInformationAdmissionDateNA: value False- Discharge date (dd-mmm-yyyy): value 28-Apr-2023- IsEventInformationDischargeDateNA: value False- Classification of the adverse event: value Hospitalization- 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 No.
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		<ul style="list-style-type: none">- Detail all possible and suspected causes including relevant medical history: value There is a possibility that the connection of screws with the acetabulum is stiff enough to cause a fracture of the pubis bone.- Current clinical status: value Under the observation.- Severity: value Moderate- Causality: relationship to study medical device: value Probable- Causality: relationship to study procedure: value NotRelated- Expectedness: value Unanticipated- Action taken: value NotPharmacological- 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 Diagnostics- computed tomography- 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:
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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 24-Apr-2023- Serious Event: value True- Id: value 1063- Notes: value <empty>
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