

## Serious Adverse Event Report

Event 24-Apr-2023 - report of 17-May-2023 - 12:15 UTC, revision 2

Initial Report Date	17-May-2023
Date of this report	17-May-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 Białecki
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	Ongoing
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
17-May-2023	12:15:16 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> <li>- ReportType: from <b>Follow-up</b> to <b>Initial</b></li> <li>- Event narrative: from <b>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.</b> to <b>A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip.</b></li> <li>- Causality: relationship to study procedure: from <b>Not Related</b> to <b>Causal relationship (related)</b></li> <li>- Action taken regarding study device / Other: from <b>&lt;empty&gt;</b> to <b>&lt;empty&gt;</b></li> <li>- Detailed treatment: from <b>Diagnostics- computed tomography</b> to <b>Diagnostics of periprosthetic fracture- computed tomography</b></li> <li>- Notes: from <b>&lt;empty&gt;</b> to <b>&lt;empty&gt;</b></li> </ul>
17-May-2023	10:23:48 (UTC)	Julia Macias (maciasjulia@gmail.com)	<ul style="list-style-type: none"> <li>- ReportType: value <b>FollowUp</b></li> </ul>

			<ul style="list-style-type: none"> <li>- Initial Report Date: value <b>17-May-2023</b></li> <li>- Report Date: value <b>17-May-2023</b></li> <li>- Date of Study Team Aware: value <b>26-Apr-2023</b></li> <li>- Time team became aware (24 hr clock): value <b>10:38:00</b></li> <li>- Title of clinical study: value <b>DELTA Revision study</b></li> <li>- Protocol ID: value <b>H-34</b></li> <li>- Name of the healthcare facility: value <b>Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP</b></li> <li>- Name of the Principal Investigator: value <b>Jerzy Biłdecki</b></li> <li>- Name of the medical device involved: value <b>Delta revision cup</b></li> <li>- IsMedicalDeviceNameNA: value <b>False</b></li> <li>- Components involved: value <b>Delta revision cup</b></li> <li>- IsMedicalDeviceComponentsNA: value <b>False</b></li> <li>- ID number of study subject: value <b>101 - 17</b></li> <li>- Age: value <b>75</b></li> <li>- Gender: value <b>Female</b></li> <li>- Attribution within the clinical investigation: value <b>TreatmentGroup</b></li> <li>- Adverse Event (diagnosis, if known, or signs/symptoms):</li> </ul>
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			<p>value <b>Periprosthetic fracture- fracture of right pubis bone</b></p> <p>- Event narrative: value <b>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.</b></p> <p>- Admission date (dd-mmm-yyyy): value <b>26-Apr-2023</b></p> <p>- IsEventInformationAdmissionDateNA: value <b>False</b></p> <p>- Discharge date (dd-mmm-yyyy): value <b>28-Apr-2023</b></p> <p>- IsEventInformationDischargeDateNA: value <b>False</b></p> <p>- Classification of the adverse event: value <b>Hospitalization</b></p> <p>- Outcome of the event: value <b>Ongoing</b></p> <p>- Outcome / Recovered date: value <b>&lt;empty&gt;</b></p> <p>- Outcome / Recovered with sequelae date: value <b>&lt;empty&gt;</b></p> <p>- Outcome / Fatal date: value <b>&lt;empty&gt;</b></p> <p>- Relevant concomitant drugs and date of administration: value <b>No.</b></p> <p>- Detail all possible and suspected causes including relevant medical history: value <b>There is a possibility that the connection of screws with the acetabulum is stiff enough to cause a fracture of the pubis bone.</b></p> <p>- Current clinical status: value <b>Under the observation.</b></p> <p>- Severity: value <b>Moderate</b></p> <p>- Causality: relationship to study medical device:</p>
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			<ul style="list-style-type: none"> <li>value <b>Probable</b></li> <li>- Causality: relationship to study procedure: value <b>NotRelated</b></li> <li>- Expectedness: value <b>Unanticipated</b></li> <li>- Action taken: value <b>NotPharmacological</b></li> <li>- Was the device permanently removed?: value <b>False</b></li> <li>- If yes, then please specify date of removal surgery: value <b>&lt;empty&gt;</b></li> <li>- Action taken regarding study device / Other: value <b>&lt;empty&gt;</b></li> <li>- Detailed treatment: value <b>Diagnostics- computed tomography</b></li> <li>- Attachments / Relevant medical history: value <b>False</b></li> <li>- Attachments / Relevant medical records: value <b>False</b></li> <li>- Attachments / Laboratory Results: value <b>False</b></li> <li>- Attachments / Imaging Methods (e.g., X-ray, CT-scan): value <b>True</b></li> <li>- Attachments / Other: value <b>False</b></li> <li>- Attachments / Other / Specify: value <b>&lt;empty&gt;</b></li> <li>- Submitter: value <b>Investigator</b></li> <li>- Name of submitter: value <b>Julia Macias</b></li> <li>- Event Onset: value <b>24-Apr-2023</b></li> <li>- Serious Event:</li> </ul>
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			<div>value <b>True</b></div> <div>- Id:</div> <div>value <b>1063</b></div> <div>- Notes:</div> <div>value <b>&lt;empty&gt;</b></div>
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