

5 Report

Serious Adverse Event Report

Event 20-Oct-2021 - report of 04-Nov-2022 - 08:57 UTC, revision 4

Initial Report Date	03-Feb-2022
Date of this report	04-Nov-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	5
Event onset	20-Oct-2021
Report type	Final
Date of Study Team Aware	20-Oct-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 Białecki
Name of the medical device involved	Revision Hip /Anca
Components involved	Stem17mm/200mm
ID number of study subject	101 - 5
Age	76
Gender	Female
Attribution within the clinical investigation	TreatmentGroup

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Adverse Event (diagnosis, if known, or signs/symptoms)	Intraoperative fracture of femur shaft
Event narrative	The femur shaft was weakened beacuse of previous use of metal loop;
Admission date (dd-mmm-yyyy)	18-Oct-2021
Discharge date (dd-mmm-yyyy)	27-Oct-2021
Classification of the adverse event	Hospitalization
Outcome of the event	Recovered 22-Nov-2021
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical histor	The femur shaft was weakened beacuse of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofit;
Current clinical status	On the first control visit 22 Nov 2021 patient is walking with 2 crutches;
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	Other intraoperative reduction and fixation of the fracture
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: 101/5

Form: Adverse event

Date	Time	User	Values
04-Nov-2022	08:57:35 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Expectedness: from Anticipated to N/A
04-Jul-2022	13:56:59 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: from Initial to Final
04-Jul-2022	13:56:06 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Outcome of the event: from Ongoing to Recovered - Outcome / Recovered date: from <empty> to 22-Nov-2021 - Notes: from <empty> to <empty>
03-Feb-2022	09:24:51 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value Initial - Initial Report Date: value 03-Feb-2022 - Report Date: value 03-Feb-2022 - Date of Study Team Aware: value 20-Oct-2021 - Time team became aware (24 hr clock):

			<ul style="list-style-type: none"> 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 Revision Hip /Anca - IsMedicalDeviceNameNA: value False - Components involved: value Stem17mm/200mm - IsMedicalDeviceComponentsNA: value False - ID number of study subject: value 101 - 5 - Age: value 76 - Gender: value Female - Attribution within the clinical investigation: value TreatmentGroup - Adverse Event (diagnosis, if known, or signs/symptoms): value Intraoperative fracture of femur shaft - Event narrative: value The femur shaft was weakened beacuse of previous use of metal loop; - Admission date (dd-mmm-yyyy): value 18-Oct-2021 - IsEventInformationAdmissionDateNA:
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			<ul style="list-style-type: none"> value False - Discharge date (dd-mmm-yyyy): value 27-Oct-2021 - IsEventInformationDischargeDateNA: value False - Classification of the adverse event: value Hospitalization - Outcome of the event: value Ongoing - Outcome / Recovered date: value <empty> - Outcome / Recovered with sequelae date: value <empty> - Outcome / Fatal date: value <empty> - Relevant concomitant drugs and date of administration: value <empty> - Detail all possible and suspected causes including relevant medical history: value The femur shaft was weakened because of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofit; - Current clinical status: value On the first control visit 22 Nov 2021 patient is walking with 2 crutches; - Severity: value Severe - Causality: relationship to study medical device: value NotRelated - Causality: relationship to study procedure: value NotRelated - Expectedness: value Anticipated - Action taken: value Other - Was the device permanently removed?:
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			<p>value False</p> <p>- If yes, then please specify date of removal surgery: value <empty></p> <p>- Action taken regarding study device / Other: value intraoperative reduction and fixation of the fracture</p> <p>- Detailed treatment: value <empty></p> <p>- Attachments / Relevant medical history: value False</p> <p>- Attachments / Relevant medical records: value False</p> <p>- Attachments / Laboratory Results: value False</p> <p>- Attachments / Imaging Methods (e.g., X-ray, CT-scan): value False</p> <p>- Attachments / Other: value False</p> <p>- Attachments / Other / Specify: value <empty></p> <p>- Submitter: value Investigator</p> <p>- Name of submitter: value Julia Macias</p> <p>- Event Onset: value 20-Oct-2021</p> <p>- Serious Event: value True</p> <p>- Notes: value <empty></p>
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