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Serious Adverse Event Report

Event 20-Oct-2021 - report of 03-Feb-2022 - 09:24 UTC, revision 1

Initial Report Date	03-Feb-2022
Date of this report	03-Feb-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	Initial
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 Bialecki
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 because 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	Ongoing
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical history	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	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	Anticipated
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