Serious Adverse Event Report

Event 01-Dec-2021 - report of 07-Dec-2021 - 22:00 UTC, revision 2

Initial Report Date	07-Dec-2021
Date of this report	07-Dec-2021
Investigator/reporter	Pawel Bartosz
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	9
Event onset	01-Dec-2021
Report type	InitialAndFinal
Date of Study Team Aware	01-Dec-2021 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 Białecki
Name of the medical device involved	Delta Revision Cup
Components involved	Delta Revision Cup, Hemispherical module, Bone screws, insert
ID number of study subject	101 - 9
Age	60
Gender	Male
Attribution within the clinical investigation	TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)	Cup loosening
Event narrative	Early postoperative cup loosening,
Admission date (dd-mmm-yyyy)	
Discharge date (dd-mmm-yyyy)	
Classification of the adverse event	InterventionRequired
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	None
Detail all possible and suspected causes including relevant medical histor	Probable cause is technical mistake at first operation with Delta Revision implantation. Too proximal cup implantation and not sufficient cup hook stabilization at the ischial bone. Second cause could be wrong position of stable stem, various position in femur.
Current clinical status	Patient undergone revision surgery at 2021-12-03, with cup and stem reimplantation.
Severity	Severe
Causality: relationship to study medical device	Probable
Causality: relationship to study procedure	Probable
Expectedness	NA
Action taken	
Was the device permanently removed?	Yes, 03-Dec-2021
Detailed treatment	Revision surgery with cup and stem removal. Reimplantation Trident Multihole cup with augment and Restoration stem.
Relevant medical history	None

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Relevant medical records	None
Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	Available
Other (please specify)	None
Submitter	Investigator
Name of submitter	Pawel Bartosz