

9 Report

Serious Adverse Event Report

Event 01-Dec-2021 - report of 07-Dec-2021 - 21:59 UTC, revision 1

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 Bialecki

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

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| 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 history | 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 | Available |
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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 |